Vacuum Gun-Adapter for SenoRx EnCor®

Operator´s Manual

Revision 03

NORAS MRI products

Date issued: August 2015

Technical changes reserved.

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1 General Information

A prerequisite for safe and trouble-free operation is the proper observance of instructions, in particular the following points:

- To obtain accurate results, you have to use only the immobilization and positioning systems, which are intended for use with the adapter.
- Before examination with patients, it is recommended to train on a phantom. Phantoms are available via NORAS MRI products GmbH. If there is no phantom available, a grapefruit or similar can be used in order to be familiar with the system.
- Please note that the Post & Pillar marker is not screwed but plugged in with a clearly audible click until it stops and then clamped by the lateral “fixing screw of the needle guide”.
- The localization process is described in this operator´s manual.
- To receive information about new developments or accessories, please send an e-mail to mri@noras.de.
- All parts supplied here can be steam sterilized and must **always** be cleaned before use and may only be applied **sterile**. The kit consists of two adapters, so that one adapter can be sterilized while the other one is in use.
- Assistance to malfunctions such as “The needle misses the lesion” you will also find in this operator´s manual.
- For each new patient, all components of the adapter as well as the Post & Pillar marker have to be disinfected according to the disinfection instructions (Chapter 5) Please always follow the disinfection instructions for the positioning and fixing unit.

 G06	**Prescription use only** Country specific laws restrict this device to sale by or on the order of a physician, or with the descriptive designation of any other practitioner licensed by the law of the country in which he practices to use or order the use of the device. This device may only be distributed to persons who are licensed practitioners or to persons who have a prescription or other order from a licensed practitioner to purchase it.

2 Intended Use / Indication for Use

The adapters for SenoRx EnCor® have been developed for the use with the SenoRx EnCor® vacuum gun from C.R. Bard in conjunction with the NORAS Biopsy Systems (Post & Pillar, Grid).

Figure above: SenoRx EnCor® vacuum gun from C.R. Bard

The correct and safe use of the vacuum gun adapter for SenoRx EnCor® for breast biopsy requires advance expertise of the operator and detailed knowledge of the operator´s manual. These instructions must be read thoroughly before using the vacuum gun adapter for SenoRx EnCor®.

	Caution
	Carefully read the C.R. Bard operator´s manual.

3 Device Description

3.1 Definitions and Symbols

The following symbols are used in this operator´s manual:

	ISO 7000-2497	Date of Manufacture
	DIN EN 980 (5.12)	Manufacturer
	EN ISO 7000-1641	Operator´s Manual
	ISO 7000-0434B	Caution: Read the accompanying documents
	Directive 2002/96/EC	Waste products should not be disposed of with household waste e. g. at a local authority collection point
	ISO 780 DIN 55402	This way up
	ISO 7000-0621	Fragile, handle with care
	ISO 7000-0626	Store in a dry place
	ISO 7000-0632	Temperature Limit
	ISO 7000-2498	Serial Number
	DIN EN 980 (5.10)	Item Number
		Conforms with the essential requirements of Council Directive 93/42/EWG of 14 June 1993 concerning medical devices

		Warning regarding risks that may result in minor physical injury or material damage
		Warning regarding risks that may result in death or serious physical injury
		Information regarding the optimal use of the product

3.2 System Components

3.2.1 Vacuum Gun-Adapter for Post & Pillar System

For 10G:

Vacuum Gun-Adapter for Post & Pillar System		**Ref: MR10062-SE**
Post & Pillar Marker for SenoRx EnCor®		112426
Post & Pillar Needle Guide for SenoRx EnCor®		MR10014-SE
Operator´s Manual		--

For 7G:

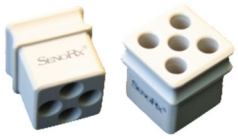
Vacuum Gun -Adapter for Post & Pillar System		**Ref: 113315**
Post & Pillar Marker for SenoRx EnCor®		113682
Post & Pillar Needle Guide for SenoRx EnCor®		117390
Operator´s Manual		--

Note! One set consists of two adapters!

	Note
	When using a vacuum gun in combination with our Post & Pillar adapters the Post & Pillar marker has to be sterilized according to our sterilization instruction. When using a steam autoclave please follow the Post & Pillar marker instruction for sterile filling. It is recommended to perform the adjustment of the coordinates with both the needle guide (contained in the set) and the inserted Post & Pillar marker. After setting the height adjustment note the adjusted height. In order to place the cannula for puncturing, exchange the needle guide with the inserted Post & Pillar marker against the sterile adapter without Post & Pillar marker. A control scan the tissue sample can now be taken.

3.2.2 Vacuum Gun-Adapter for Grid System

For 10G:

Vacuum Gun-Adapter for Grid System		**Ref: MR10061-SE**
Grid Needle Block for SenoRx EnCor® (5 holes)		MR10069-SE
Grid Needle Block for SenoRx EnCor® (4 holes)		MR10070-SE
Operator´s Manual		--

Note! One set consists of two adapters!

3.3 Safety Information

Please consider the following when using the **Vacuum Gun-Adapter for SenoRx EnCor®** (Post & Pillar- & Grid-System):

G16	**Device damage** Only trained personnel may be assigned to handle the system. Operating errors may cause permanent damages to the device.

	Bodily injuries Only trained personnel may be assigned to handle the system. Operating errors may cause bodily injuries (e.g. contusions) to the user and/or patient.

G02	**Danger of infection** Prior to start-up of the devices or parts thereof, all components must be treated as described in chapter 5 “Cleaning, Disinfection and Sterilization”. Non-compliance with the above instructions may lead to infection of the patient.

	Note Please be sure to pay attention to and comply with the safety information and instructions of the MRI device manufacturer for operators, patients and third parties.

The operator´s manual must be read by each operator prior to using this device. In order to become skilled in the proper handling of this system you should, in addition to participating in training with the system, use a phantom to become familiar with its use.

 G10	**Bodily injury of the patient** Prior to each patient examination, you should make a careful visual inspection of the system components. In case of unusual findings and/or damage found the system must not be used. Damaged parts can be sharped-edged and cause injuries to the patient and/or to the user.

 G20	**Combination with other devices** The use of other components as listed in this operator´s manual is only allowed with written permission of NORAS MRI products GmbH.

	Bodily injuries due to accessories Please follow the instructions of the accessory manufacturer. In case of biopsy needles note in particular the authorization of the field strength of the used MRI and the correlation of needle diameter and needle guide/needle block and an adequate needle length for the planned biopsy (see also Chapter 4). Non-compliance with theses instructions may lead to bodily injuries of the user or patient.

	Bodily injuries due to accessories When using accessories always observe the manufacturer's instructions.

4 Localization and Biopsy Process

	Permanent damage to the systems
	The fixation screws should be removed from the base unit fixation plate during medial application. In case of a higher load on the patient rest a damage of the screws could not be excluded

When using the grid as a medial application the fixation screws must not be mounted. The screws are only necessary as additional fixation of the grid for the lateral application. The medial grid is always mounted in the lowest possible position. It is sufficiently fixated with the ball catch.

The fixation screws are part of the standard delivery of the basic unit fixation plate. The basic unit fixation plate can be used both lateral and medial. Using the grid in lateral position it can be moved in 10 mm steps up to max. 30 mm in posterior direction. Only with this application, the screws are necessary for a safe fixation.

4.1 With Post & Pillar Biopsy System

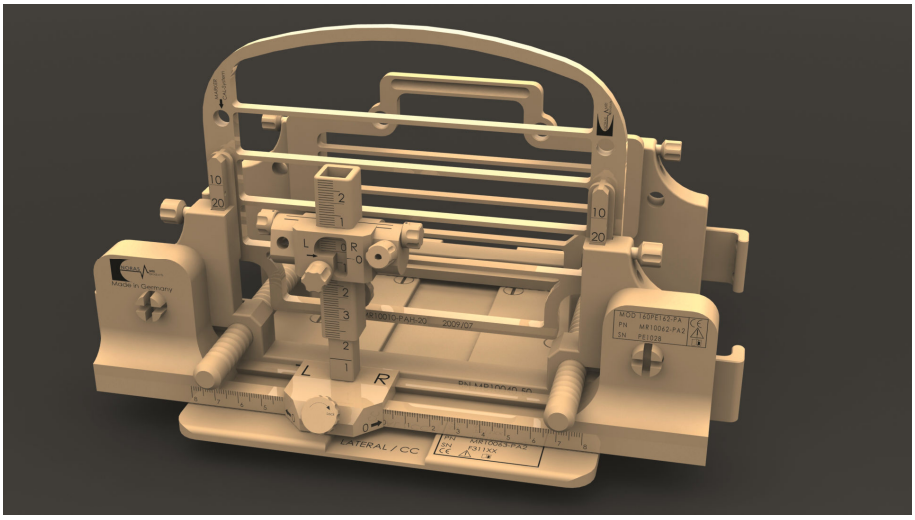
G11	**Permanent damage to the system**
	The system may only be assembled by trained medical personnel. Incorrect assembly and operator errors made by untrained personnel can permanently damage individual parts of optional components and of the device itself.

G12	**Training of personnel**
	The users must be trained before using the device (detailed training of the personnel for existing components).

In the following, the localization process with medio-lateral alignment of the fixation unit, lateral access and the use of axial slices is described. The description applies for the use of the system with the Post & Pillar Biopsy System for the examination of a single breast.

Medial and lateral access:

Push the fixation plate with the medial slat plate onto the shorter raster bars of the base plate (Ref.111292) as far as it goes.



Slide the second fixation plate with the curved slat plate onto the longer raster bars of the base plate (marked “Lateral/CC”) up to the stop. Insert the base plate into the round pits of the insertion plate of the patient rest.

After aligning the complete fixation unit in medio-lateral direction, slide the fixation plate until the end of the raster bars. The fixation unit is now open as far as possible.

For medial access, insert the blocking plate into the patient rest of the side of the breast which is not to be biopsied. Now position the patient on the patient rest and fixate the breast to be biopsied by pressing the slat plates on the raster bars against the breast.

Be careful to ensure that the patient can lie as comfortable as possible during the entire procedure. Now you have medial access below the blocking plate or lateral access from the outside.

Cranial/caudal access:

To enable cranial/caudal access proceed as described previous to provide medial/lateral access.

Please note that when the biopsy device is turned into the cranio-caudal direction, the MRI images must be made in the sagittal direction to correspond with the following description.

 G14	**Needle penetration at incorrect location** The breast must be correctly immobilized. If the breast is not immobilized properly, it might slip and the data delivered by the MRI might be inaccurate.

Ensure that as much breast tissue as possible is held between the slat plates.

Screw the filled marker into one of the needle guides (on right or left side) and reset the scales of the guide base, guide bar and the angulation angle of the needle guide of the Post & Pillar positioning unit in horizontal and vertical direction to zero (*see ill. below*).

Along the biopsy process the plastic cannula contacts with the needle guide. Thus, it is obligatory that the Post & Pillar marker is sterile.

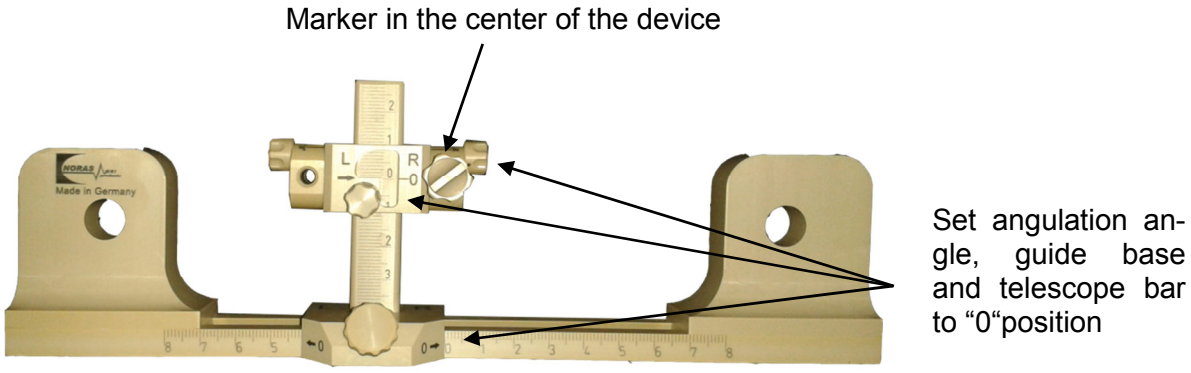
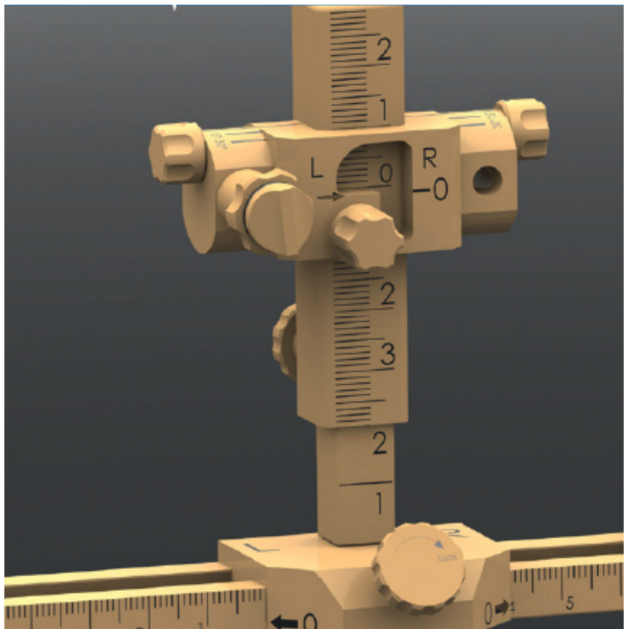
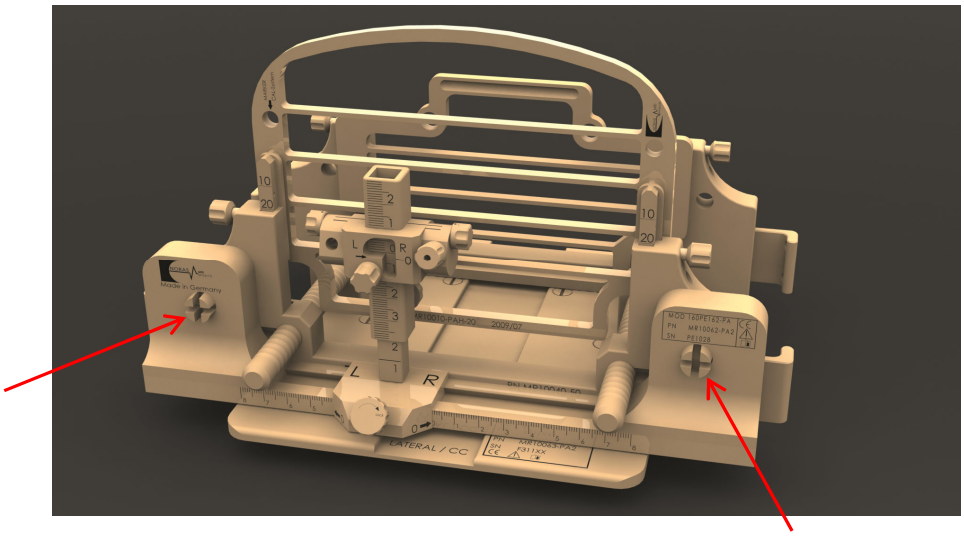


Figure above: Needle guide on zero position with marker on the right

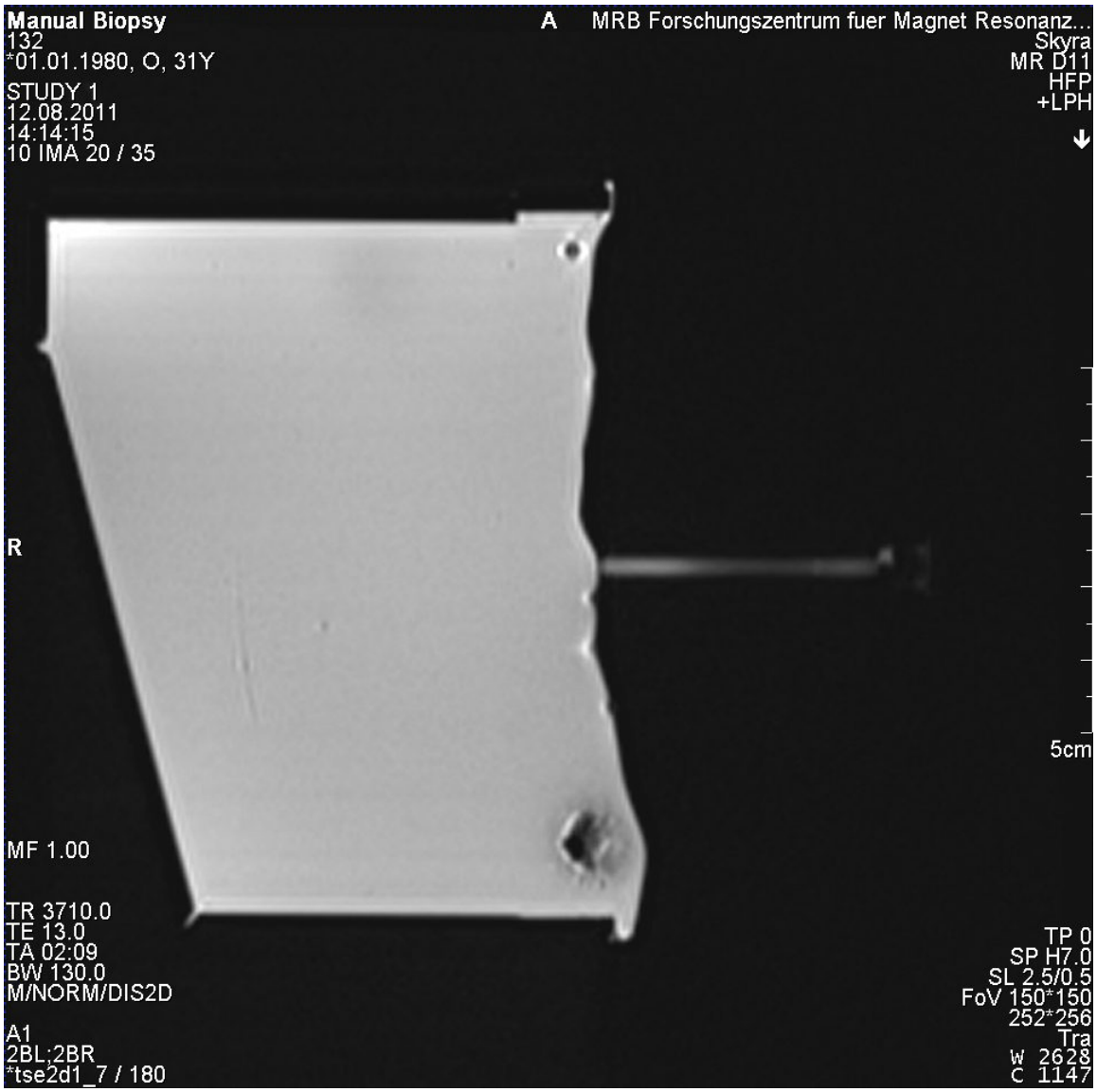


Now mount the Post & Pillar positioning unit onto the pins of the fixation plate.

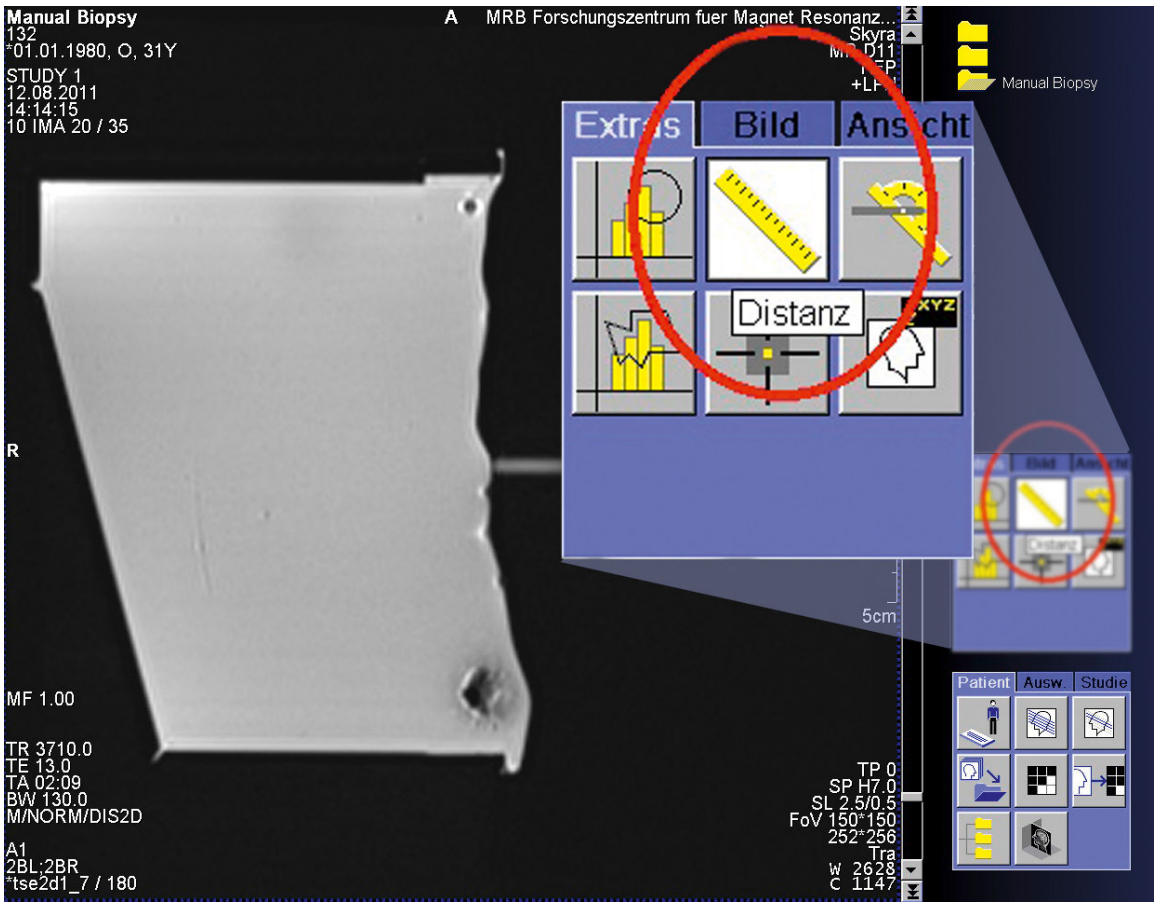


a) Manually calculation of coordinates for the MR-supported breast biopsy with the NORAS Post & Pillar Biopsy Unit on SIEMENS MR systems

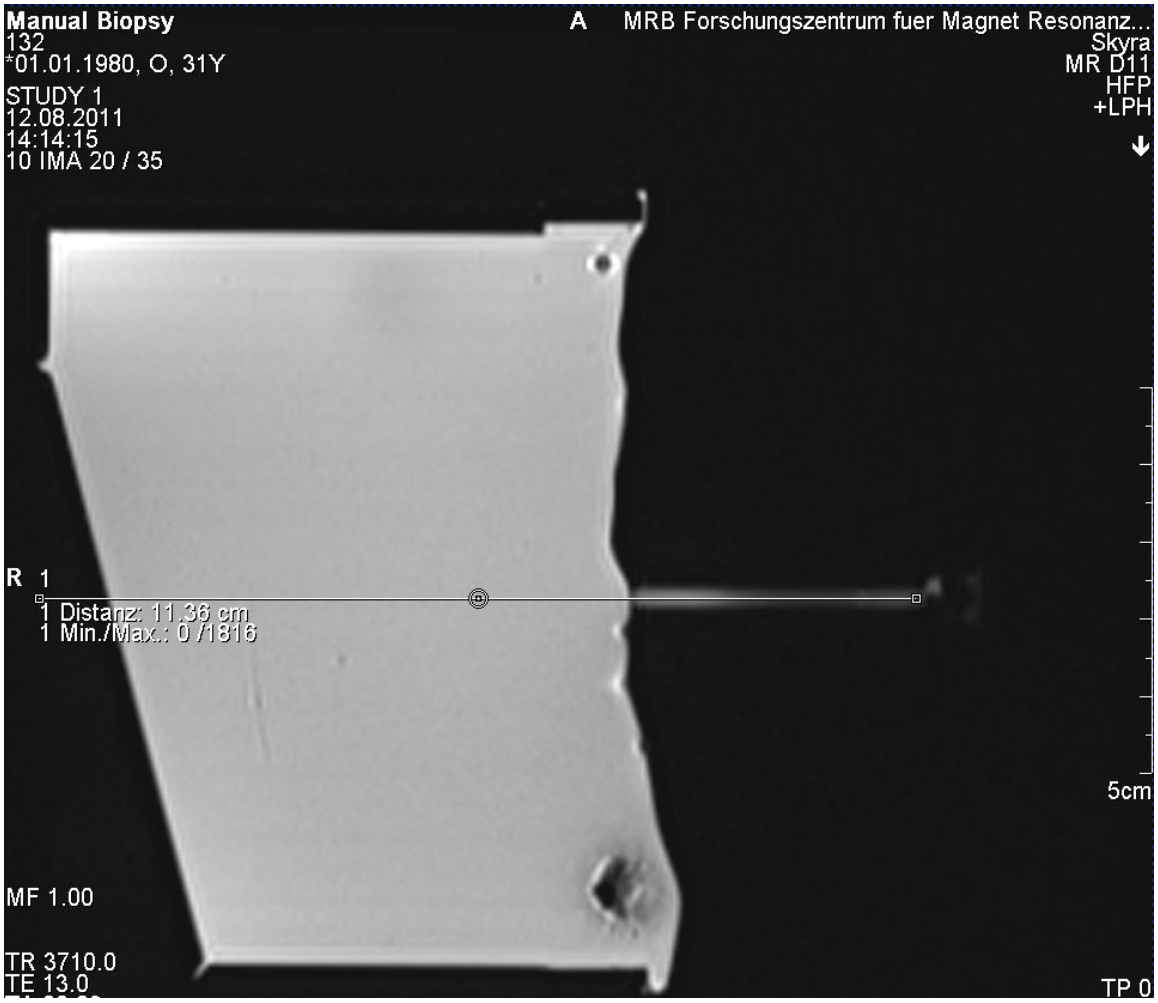
1. Perform a measurement with transversal slices and look for the slice where you can see the marker.



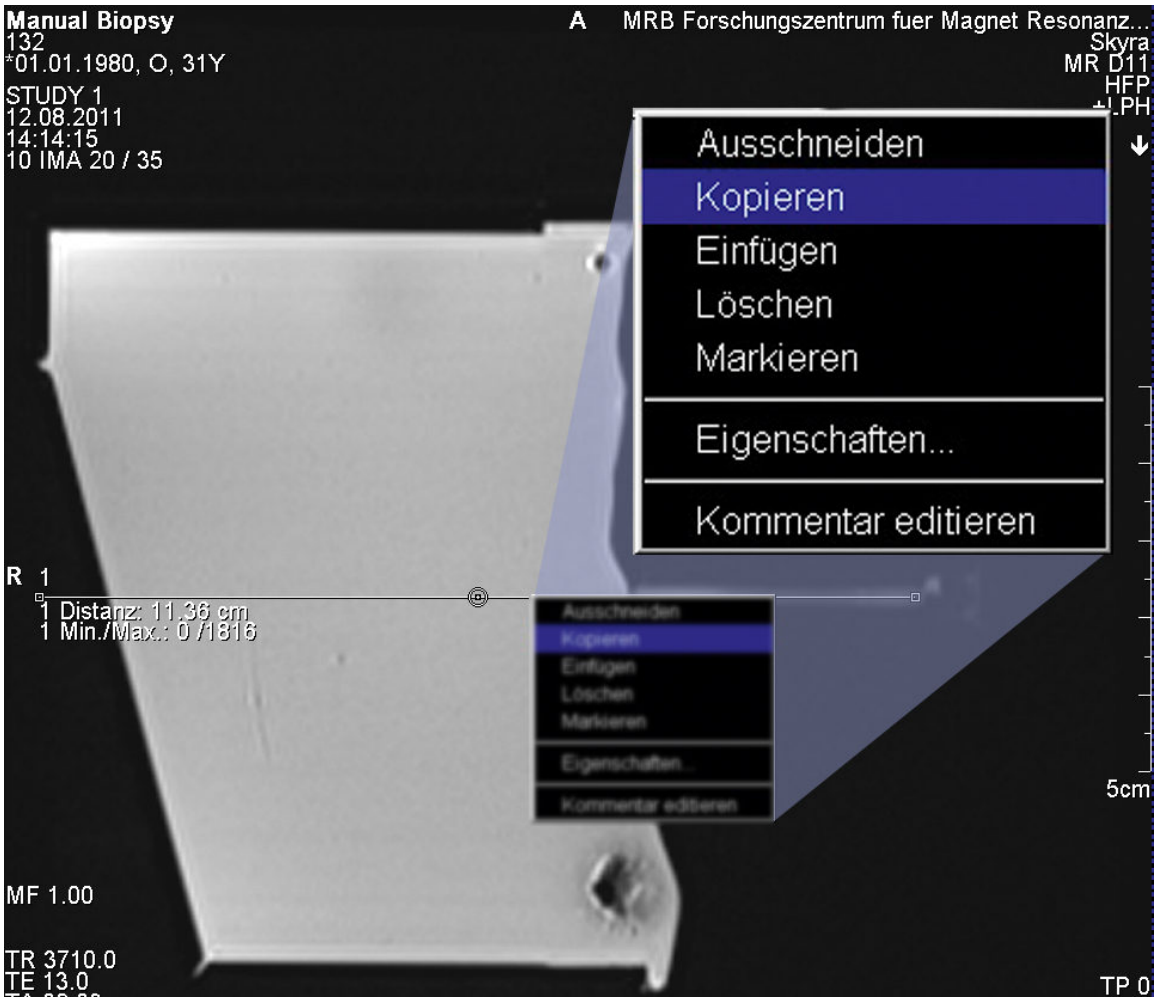
2. Start the “distance” tool (menu, right center → “Extras“ → “distance“ (ruler)).



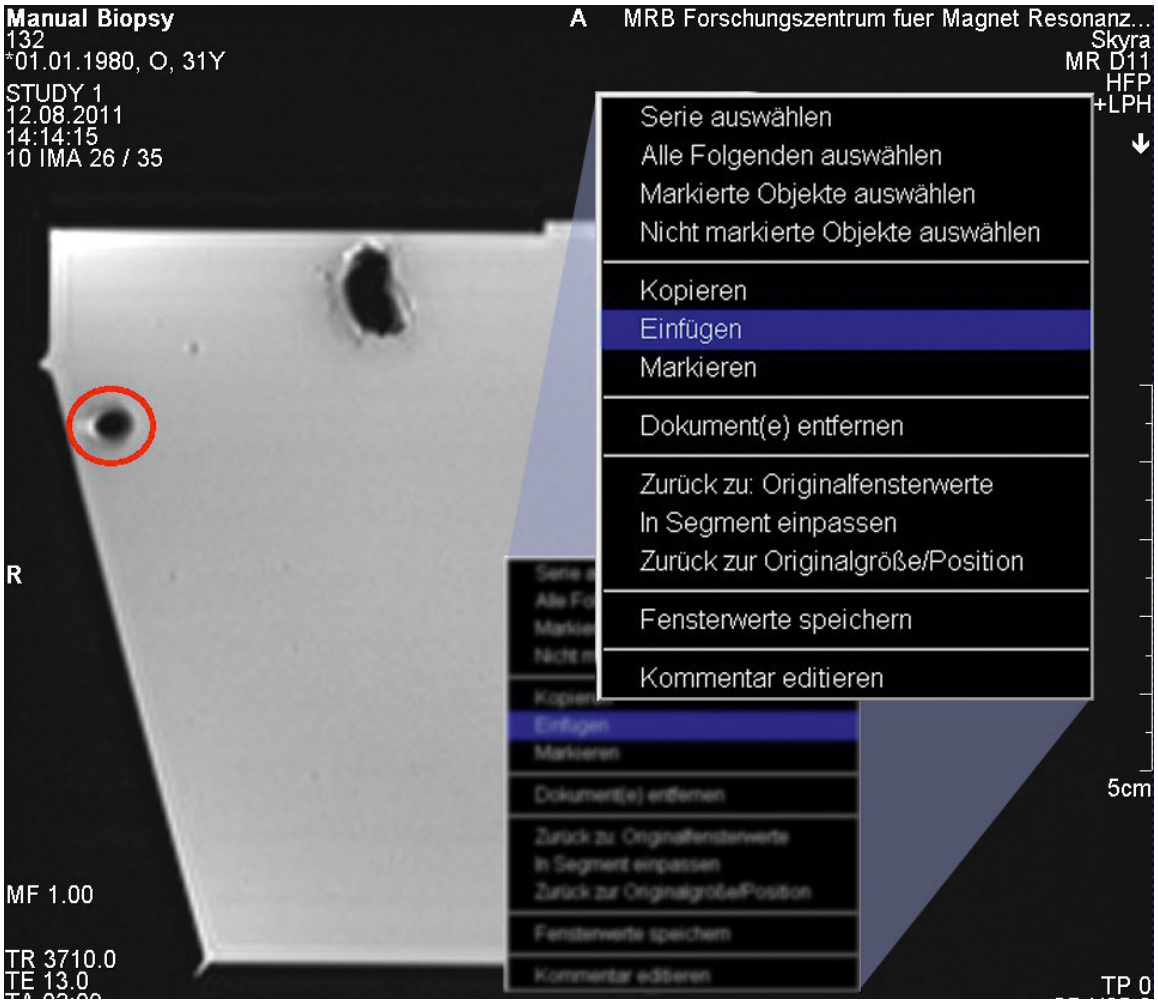
3. Draw a line, straight through the pointer.



4. Mark that line with a left-click and select the marked line with a right-click. In the context-menu, select “copy“. By doing so, the line is copied and can be pasted into other slices.

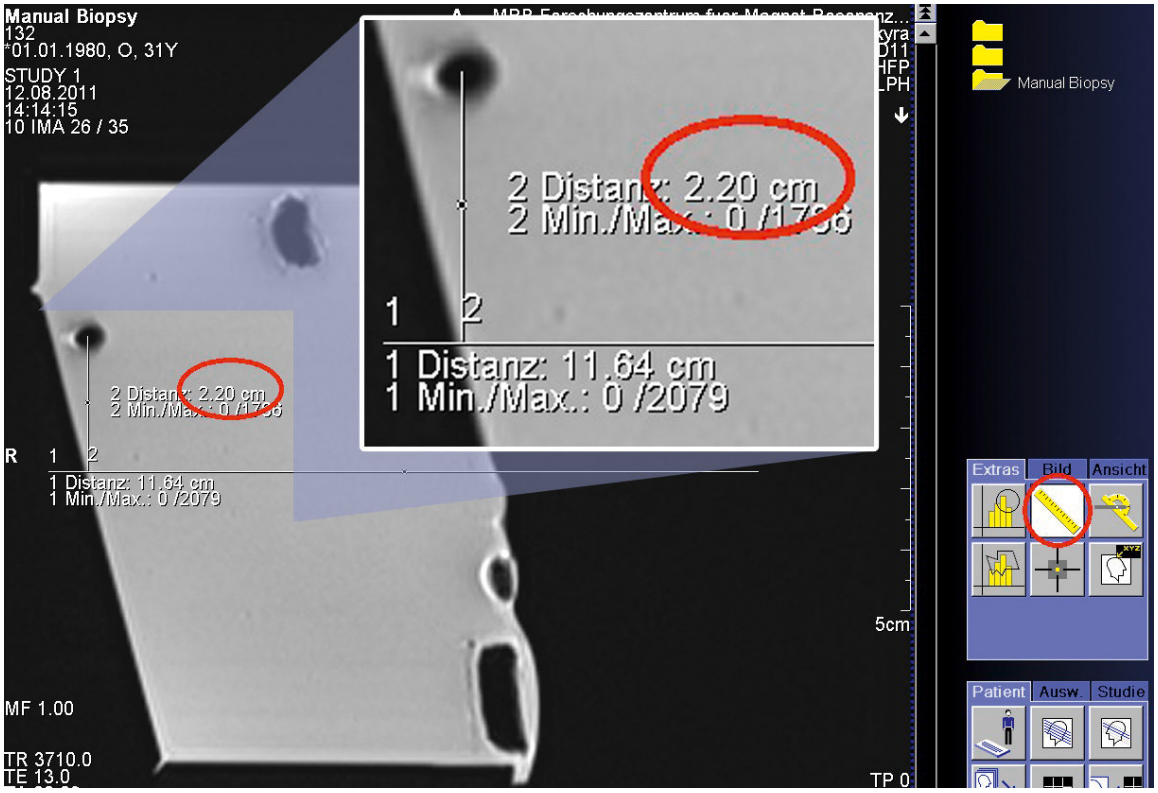


5. Scroll through the other slices until you find the lesion that you want to perform a biopsy on. Right-click on this slice and select “paste“.

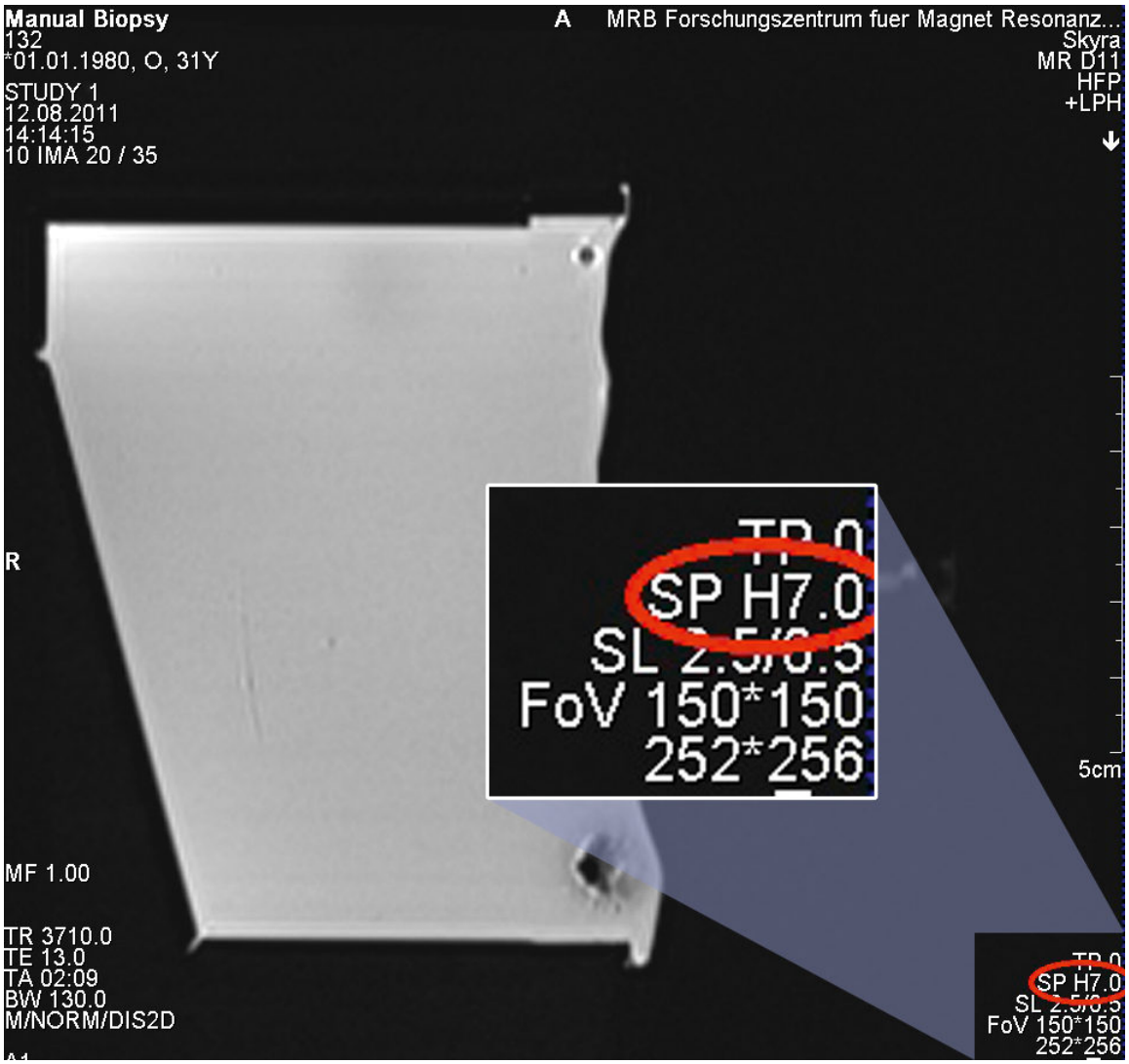


6. Select the “distance” tool again and measure the distance between the lesion and the reference line that you inserted in step 5. Please note these measurements on a separate piece of paper.

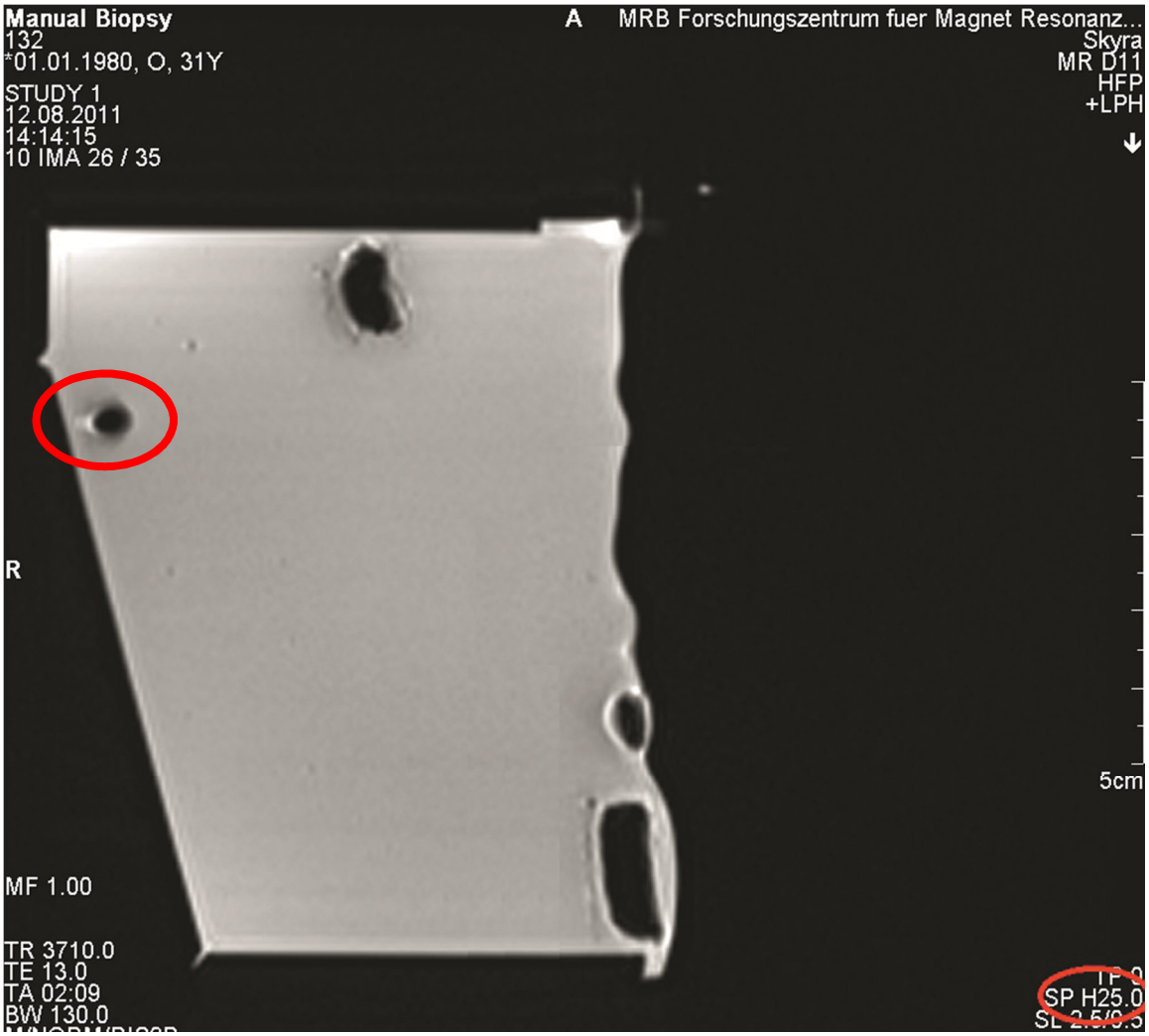
In this example the Post & Pillar positioning unit has to be moved 22 mm from the marker zero position to anterior (because the patient is lying in the prone position).



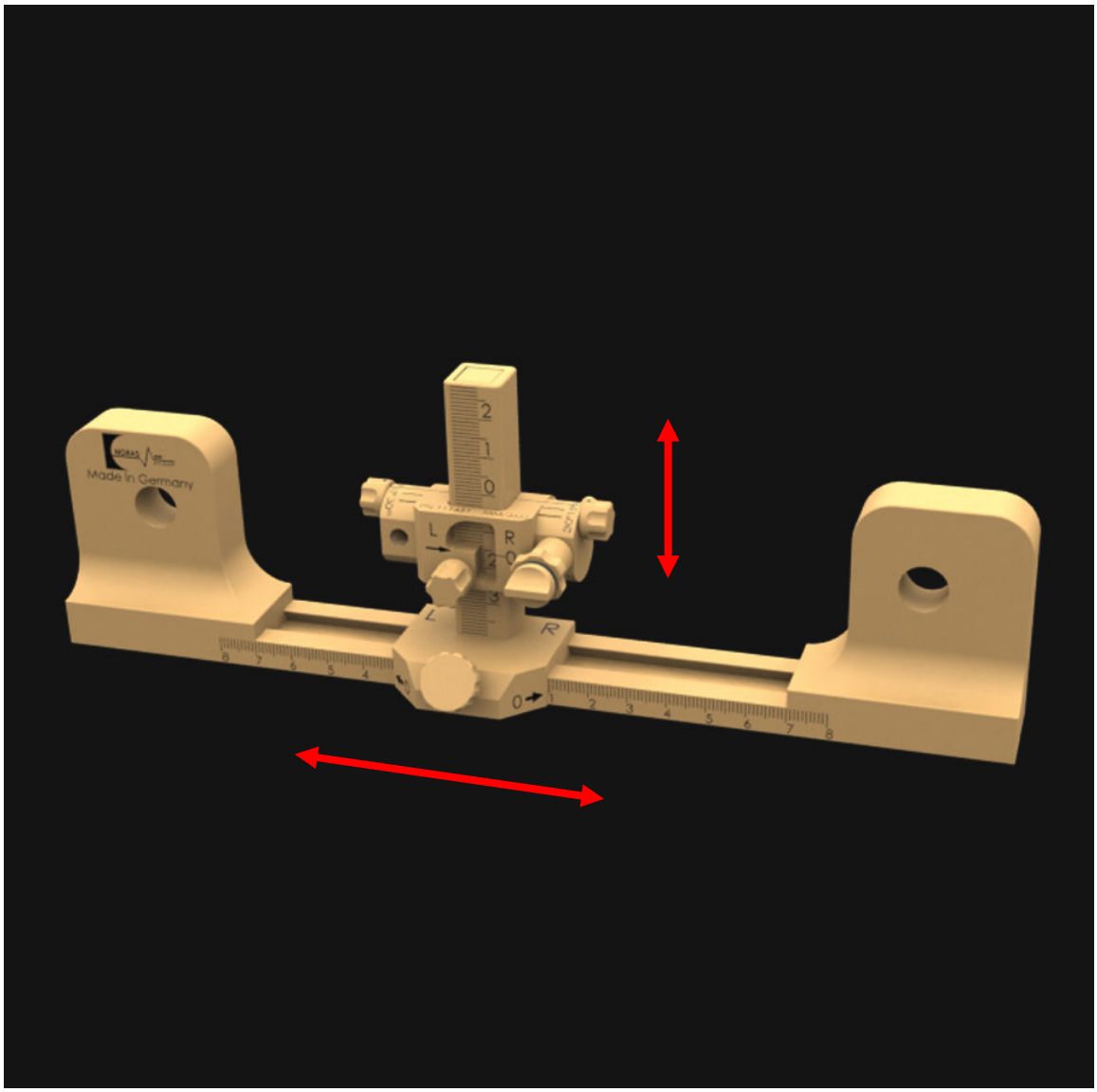
7. In order to determine the shift from head to feet (Post & Pillar positioning unit to the left or to the right), view the slice position of the marker and lesion at the transversal slices. The marker from step 1. is located on slice position (“SP“=Slice Position) H7.0, therefore 7 mm towards the head from the marker zero position.



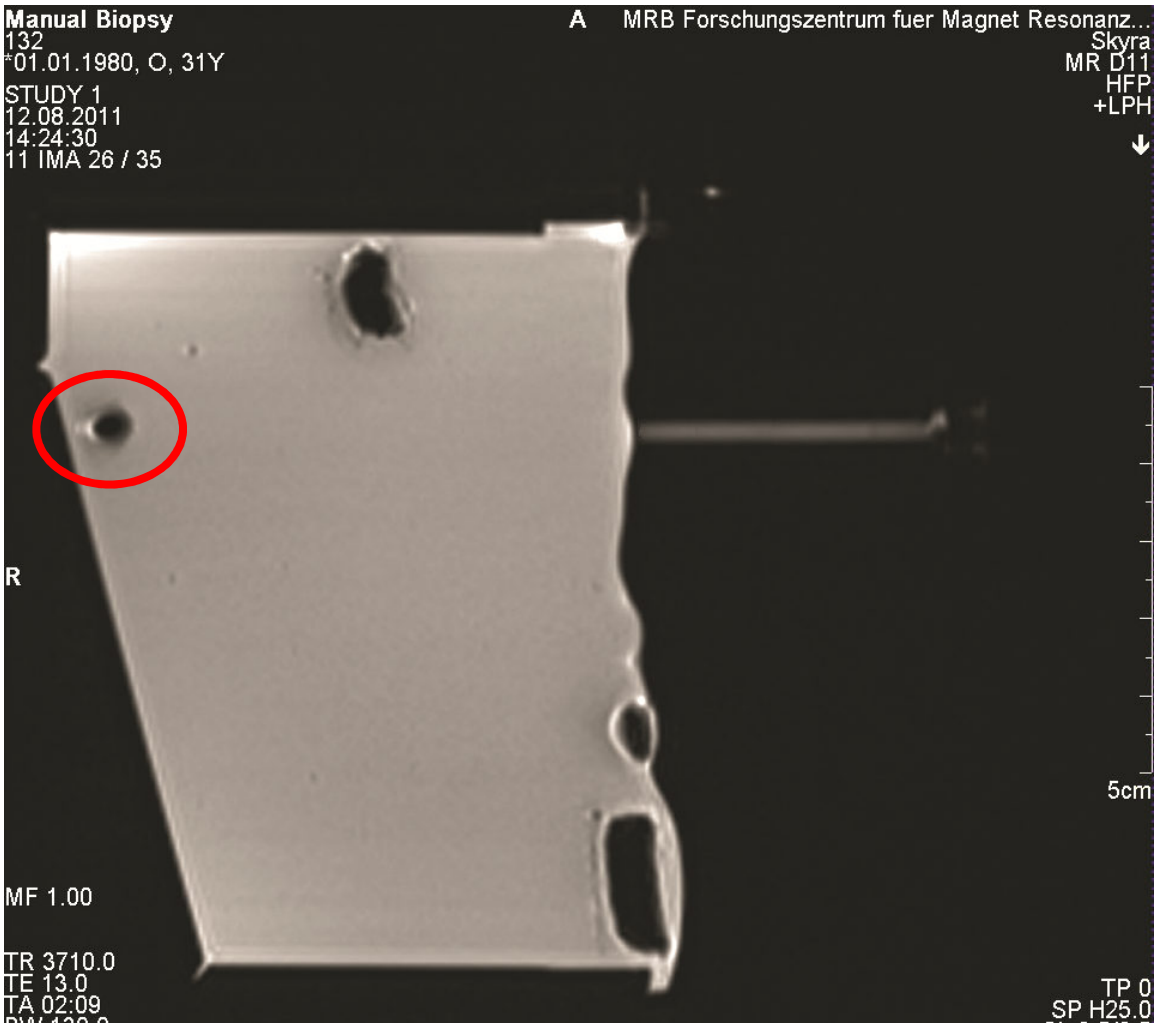
8. The lesion you have chosen in step 5. is located in our example on slice position H25.0. Hence, the difference is 25-7=18mm. In order to reach the lesion, you have to move the Post & Pillar positioning unit by 18 mm towards the head.



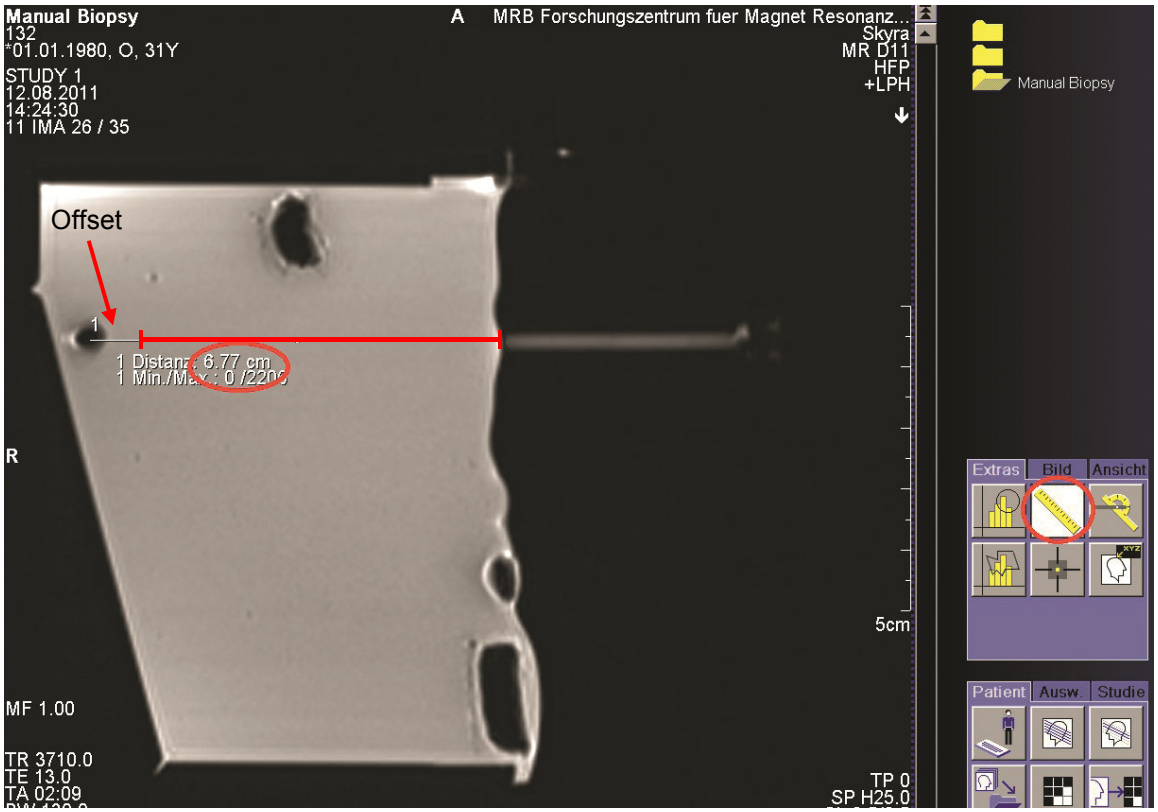
9. Move the Post & Pillar positioning unit with the marker according to the calculated coordinates (in our example 22 mm downwards (anterior) and 18 mm towards the head).



10. Perform a control scan in order to check that the marker is located in front of the lesion.



11. Use the “distance” tool again in order to measure the **puncture depth from the surface of the skin to the middle of the lesion** (in this case 68 mm). Subtract an **offset**, depending on the biopsy system (normally about **5-10 mm**), in order to position the cannula lie in front of the lesion.

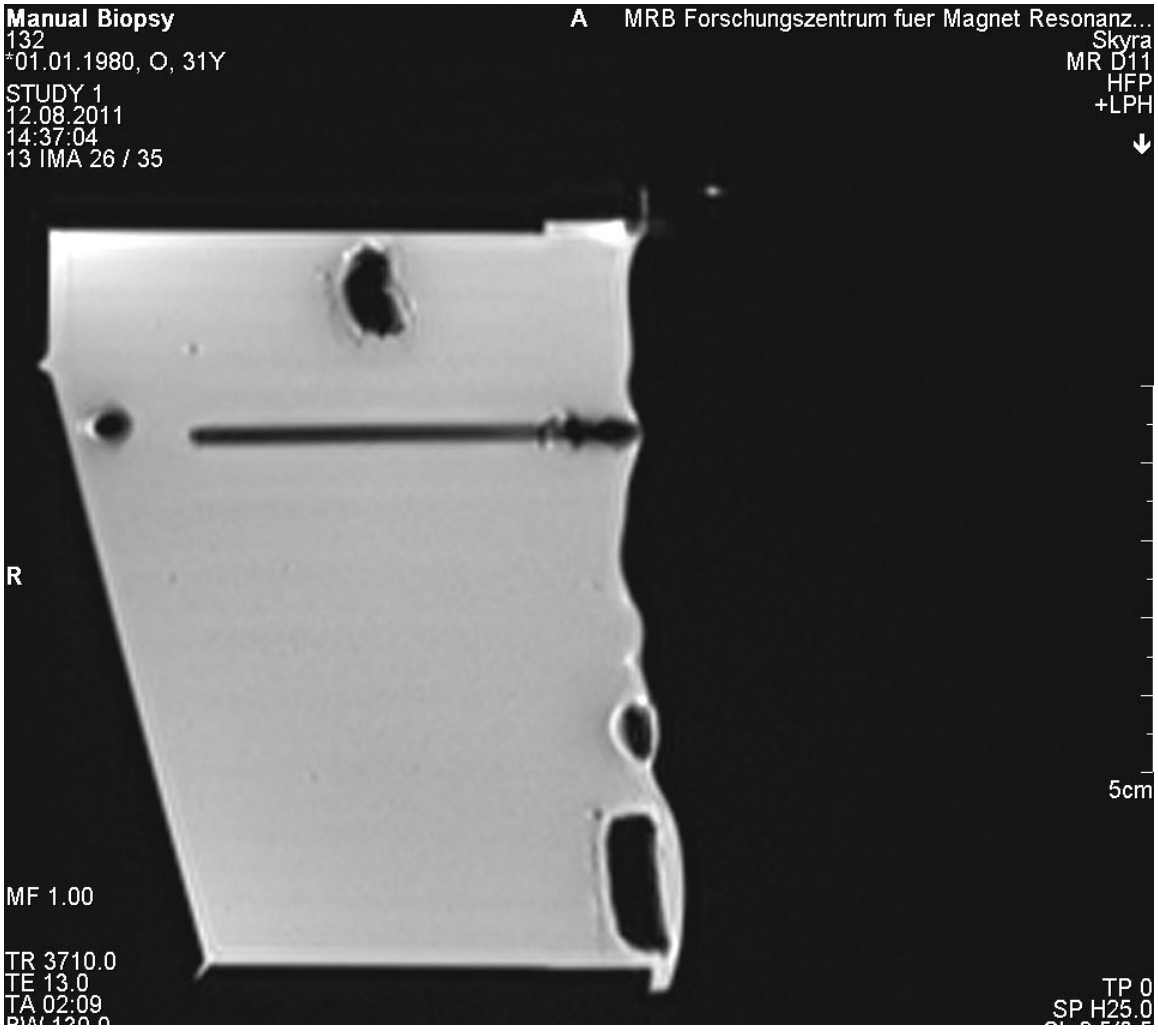


Now replace the complete Post & Pillar needle guide for your SenoRx EnCor® vacuum biopsy system with the second sterile needle guide.

	Danger of infection
	Before intervention, the complete Post & Pillar needle guide has to be replaced with the second sterile needle guide. Failure can lead to infections of the patient.

Now puncture the breast with the trocar using this offset-corrected depth (starting at skin surface). Afterwards pull the needle out of the trocar and insert the plastic-bar into the cannula instead. The plastic bar causes less artifact than the needle and prevents blood back-flow into the cannula.

12. Perform a control scan in order to check that the end of the needle is positioned in front of the lesion.



After the successful control scan the plastic bar can be removed from the cannula and you can start with the biopsy or inserting a localization wire.

Perform the biopsy in accordance with the instructions of your needle and/or vacuum manufacturer.

	Note
	Please note the application of the NORAS Post & Pillar vacuum gun adapter for SenoRx EnCor® with 10G or 7G doesn't require a needle guide sleeve. The cannula of the vacuum biopsy system is directly inserted into the Post & Pillar needle guide. The cannula is fixed by the locking screw of the angle adjustment.

After completion of the biopsy, clean the device parts as described in chapter 5 "Cleaning, Disinfection and Sterilization".

	Control scan shows large or no image distortion
	Please pay attention to removing the metal trocar when inserting the cannula. When using a plastic cannula the metal trocar has to be replaced by the provided plastic stick.

	Danger of penetration through the breast
	Should, under exceptional circumstances, the needle be bent while in the breast (e.g. if the needle should strike one of the three horizontal slats after penetrating through the breast), the clip off the distally deformed needle end with a suitable, MR-compatible tool and remove the remaining trocar. Retraction of the needle with the bent end section would injure the breast.

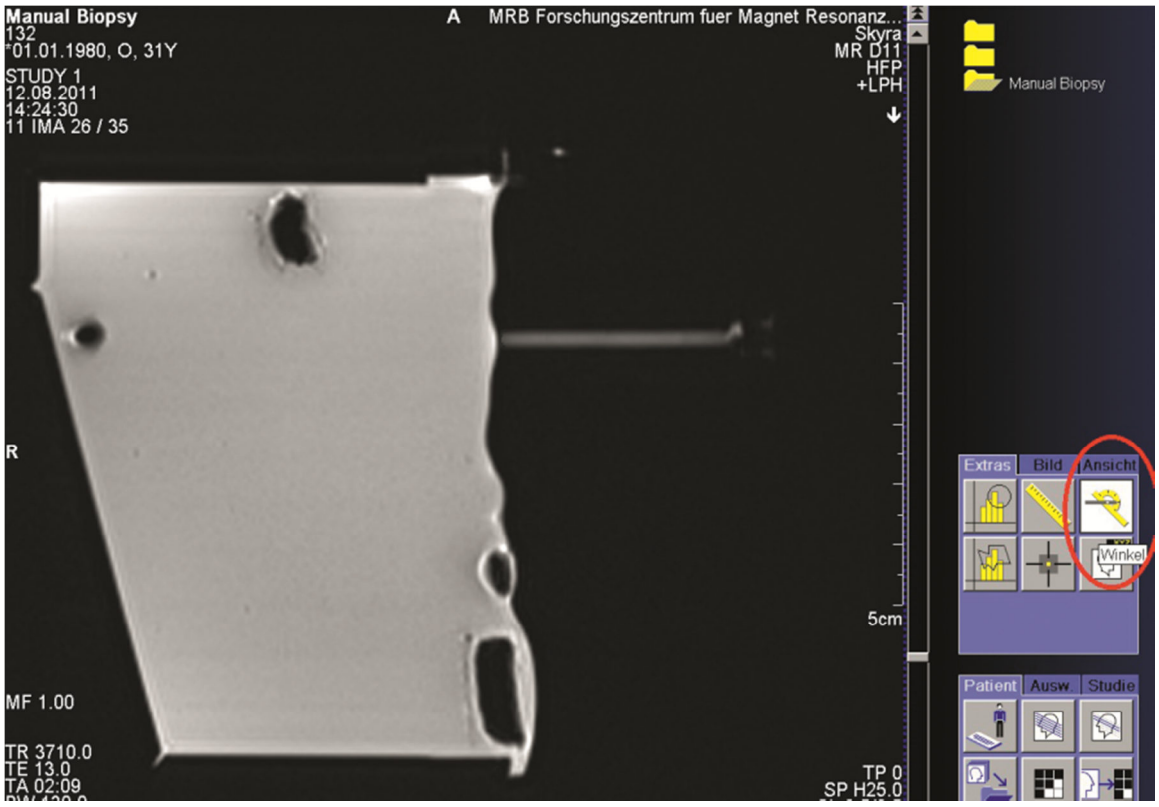
	Danger of bruising
	Be absolutely sure to loosen the slat lateral plates before withdrawing the breast. That way bruises or injuries to the patient can be avoided.

	Danger of injury
	Before loosening and withdrawing the breast, you must remove all instruments. If all instruments are not removed, you may injure the breast of the patient.

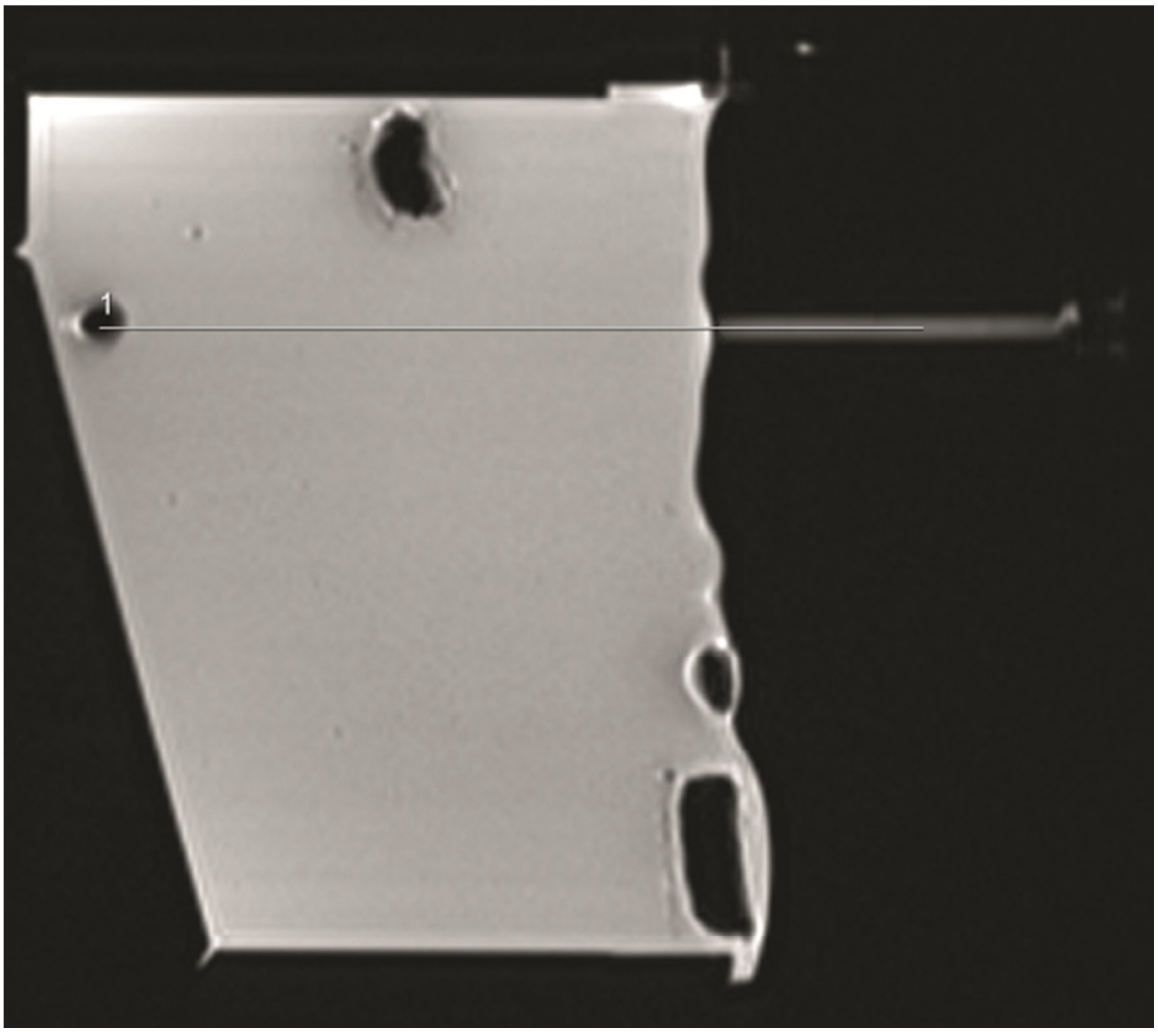
b) Angulated, manual calculation of coordinates for the MR-supported breast biopsy with the NORAS Post & Pillar Biopsy Unit on Siemens MR systems

Perform the steps 1. to 10. from the user manual for the straight, manual calculation of coordinates. If you notice during the straight biopsy that, for example, one of the bars of the grid is in the way of the biopsy, or if you prefer to continue with an angulated biopsy for any other reason, you can also work with an angulation of 15 or 30 degrees toward the top or the bottom.

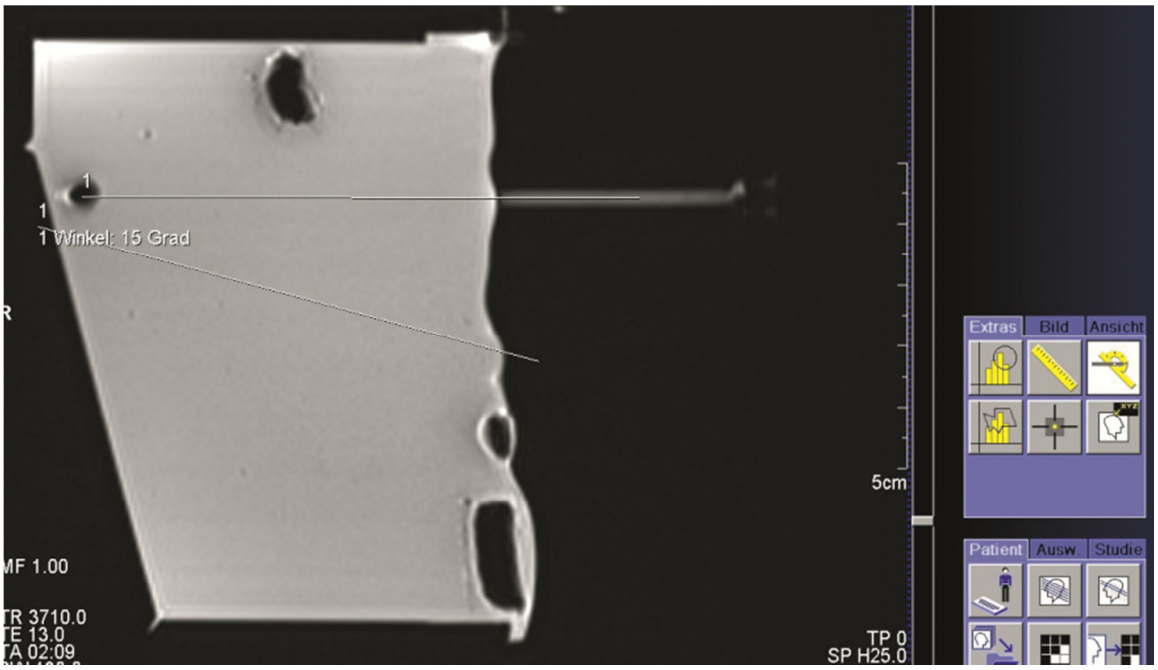
13. Now, an angle of 15 degrees (in this example) has to be drawn to the original marker line. To do so, one needs to use the tool, which you find on the right hand side under “Extras” → “angle“.



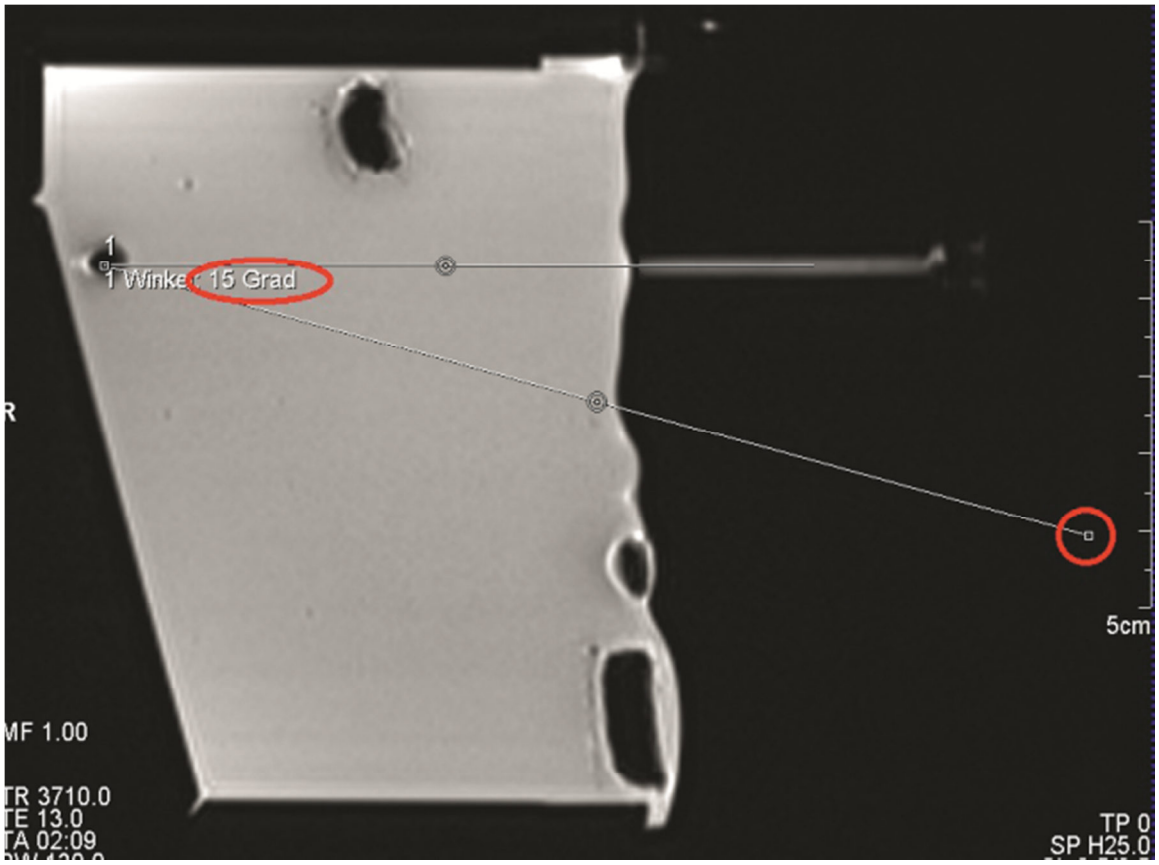
14. Draw the first line, in this example from right to left, through the marker toward the lesion.



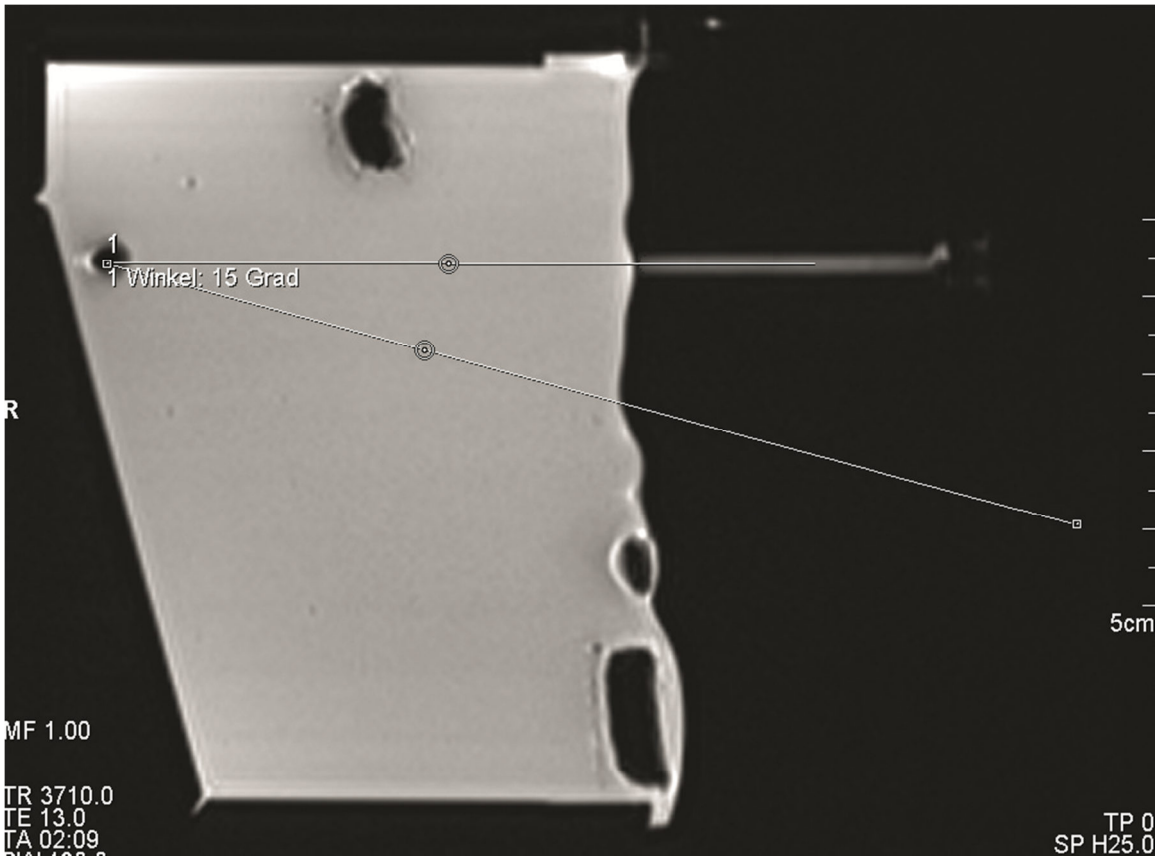
15. Draw the second line with an angle of 15 degrees from left to right. This can also be done slightly underneath the first line.



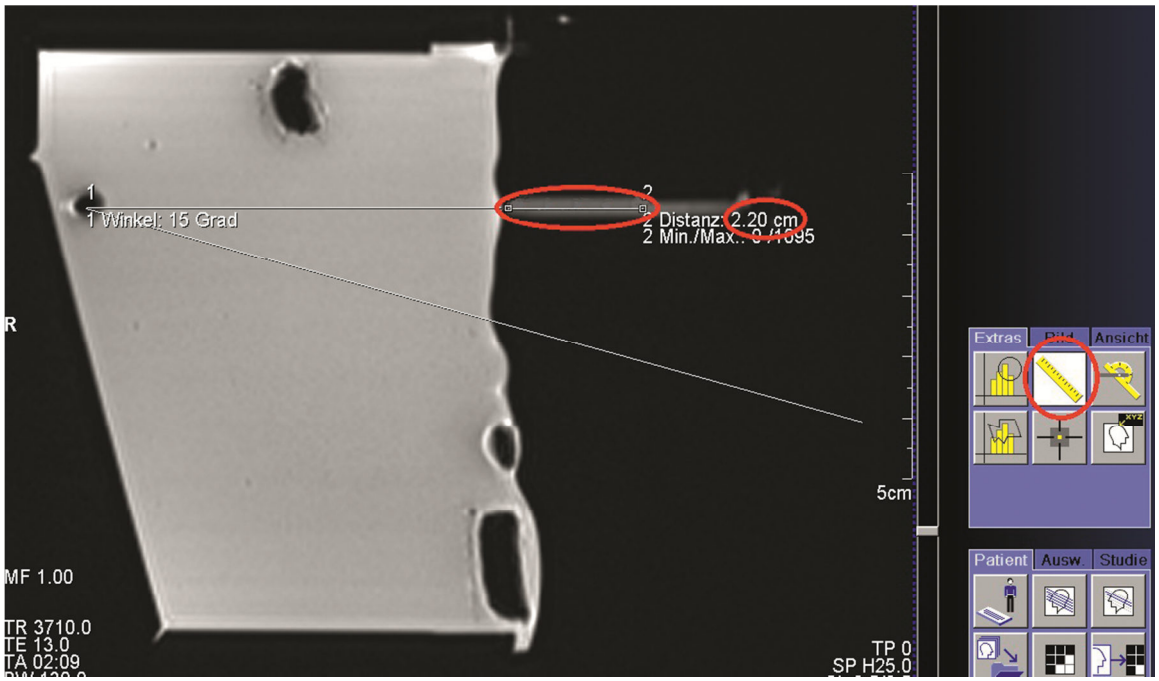
16. The second line has to have appropriate length toward the right so it lasts at least underneath the pivot point of the Post & Pillar marker. You can also extend that line afterwards by pulling its right endpoint.



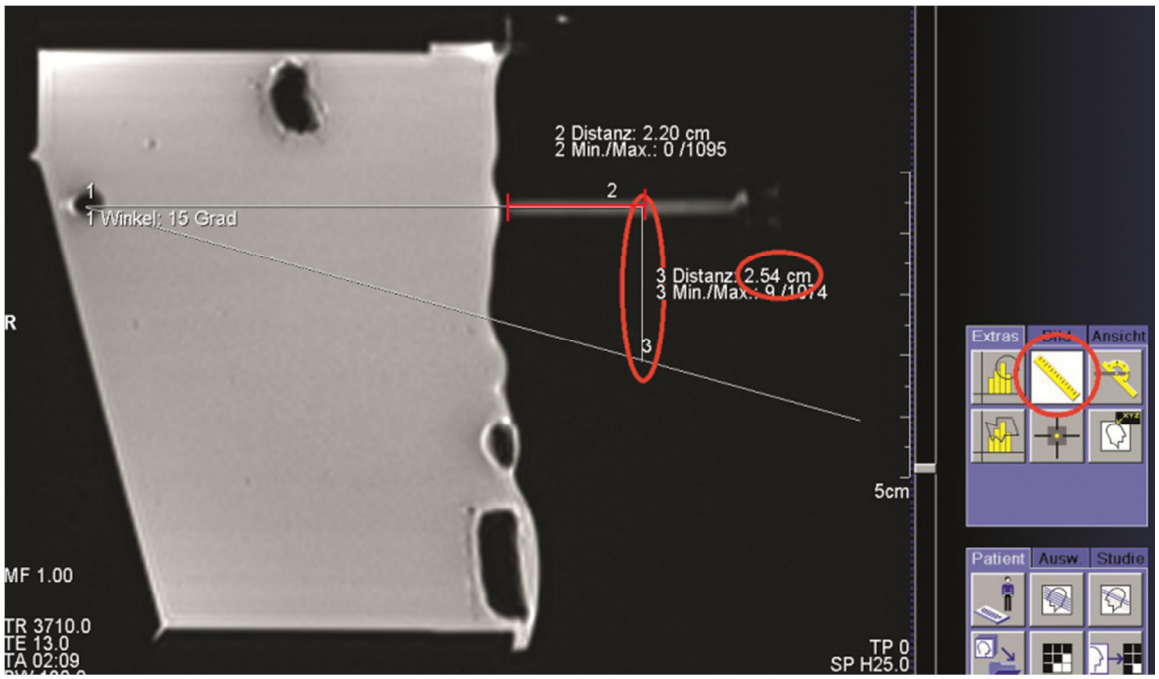
17. Now, go ahead and move the second line (which forms an angle of 15 degrees with the first line) so that it has its left endpoint in the center of the lesion. Then, left-click the second line. Finally, hold down the left mouse key and move the line.



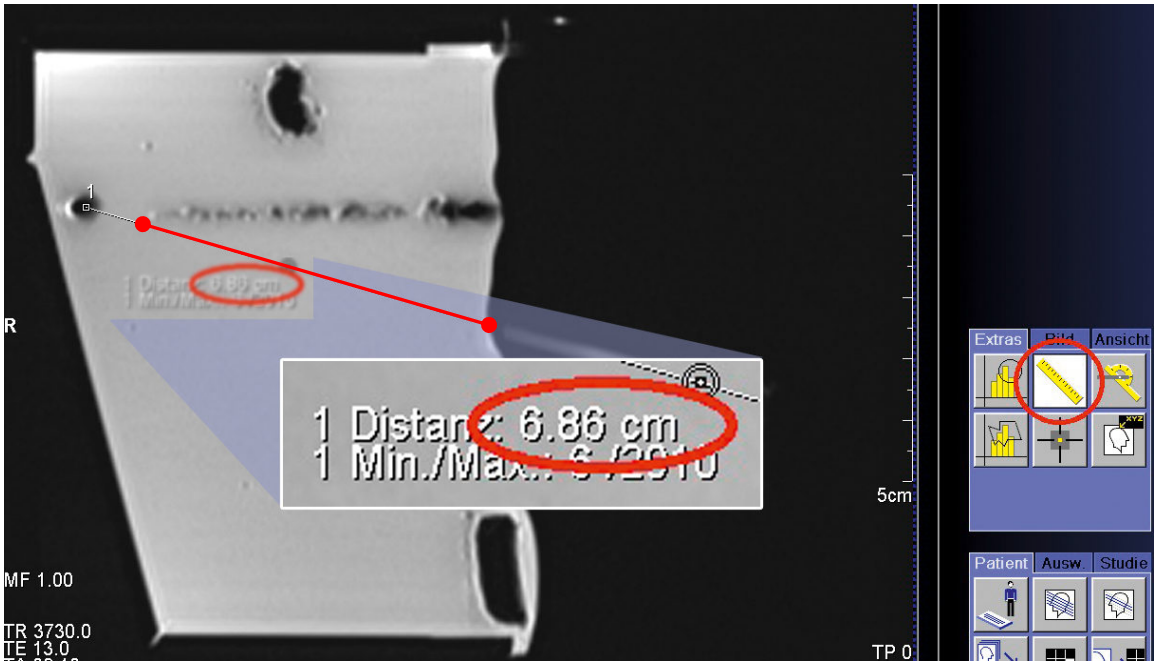
18. Choose the “distance” tool und draw the new line with a length of 22 mm from the tip of the marker to the back, where the pivot point of the mechanic is located.



19. With an additional line, measure the distance from the pivot point on the marker (22 mm behind the tip) to the line with 15 degrees angle (here 25.4 mm). This is the amount you need to move the Post & Pillar positioning unit posterior (toward the ceiling).



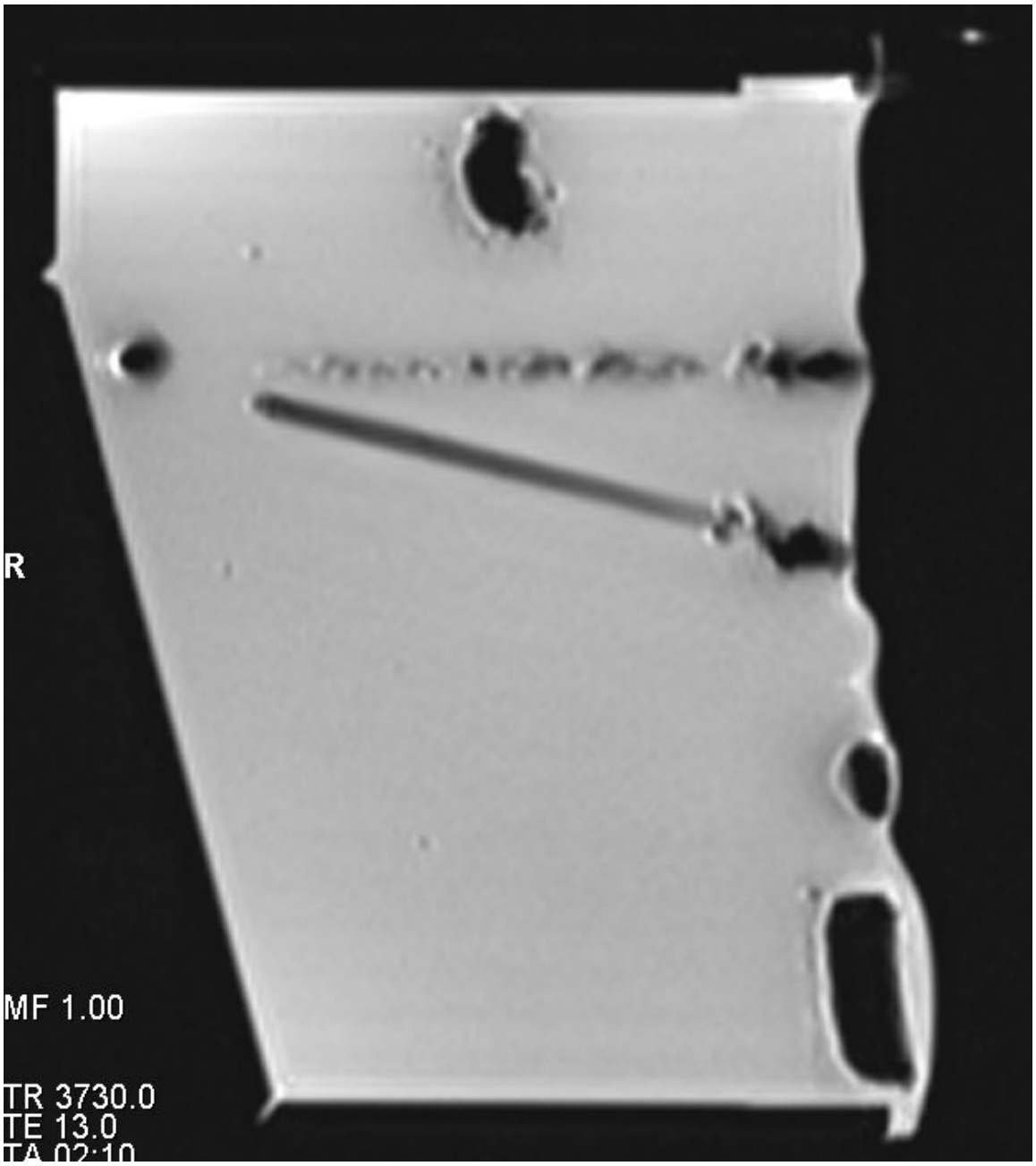
20. After movement (here 25.4 mm posterior) and angulation of the marker (here 15 degrees toward anterior, hence toward the floor), perform a control scan in order to check that the marker points at the lesion. Now, determine similarly to step 11. the **puncture depth from the skin surface to the center of the lesion** (here 68.6 mm without offset).



Now replace the complete Post & Pillar needle guide for your SenoRx EnCor® vacuum biopsy system with the second sterile needle guide.

	Danger of infection
	Before intervention, the complete Post & Pillar needle guide has to be replaced with the second sterile needle guide. Failure can lead to infections of the patient.

21. After the puncture with the trocar, perform another control scan in order to check that the end of the cannula lies right in front of the lesion.



After the successful control scan the plastic bar can be removed from the cannula and you can start with the biopsy or inserting a localization wire.

Perform the biopsy in accordance with the instructions of your needle and/or vacuum manufacturer.

	Note
	Please note the application of the NORAS Post & Pillar vacuum gun adapter for SenoRx EnCor® with 10G or 7G doesn't require a needle guide sleeve. The cannula of the vacuum biopsy system is directly inserted into the Post & Pillar needle guide. The cannula is fixed by the locking screw of the angle adjustment.

After completion of the biopsy, clean the device parts as described in chapter 5 "Cleaning, Disinfection and Sterilization".

	Control scan shows large or no image distortion
	Please pay attention to removing the metal trocar when inserting the cannula. When using a plastic cannula the metal trocar has to be replaced by the provided plastic stick.

	Danger of penetration through the breast
	Should, under exceptional circumstances, the needle be bent while in the breast (e.g. if the needle should strike one of the three horizontal slats after penetrating through the breast), the clip off the distally deformed needle end with a suitable, MR-compatible tool and remove the remaining trocar. Retraction of the needle with the bent end section would injure the breast.

	Danger of bruising
	Be absolutely sure to loosen the slat lateral plates before withdrawing the breast. That way bruises or injuries to the patient can be avoided.

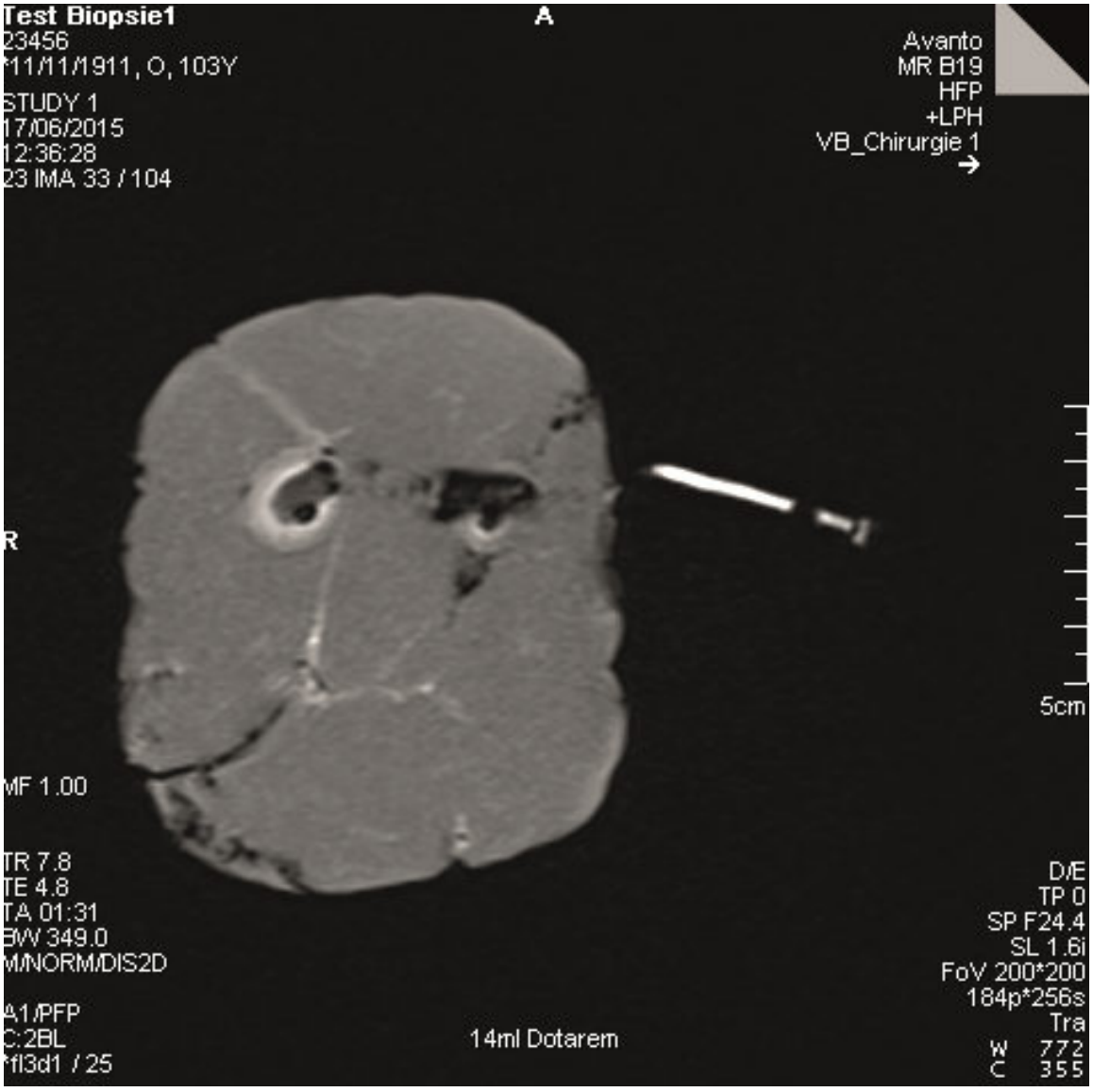
	Danger of injury
	Before loosening and withdrawing the breast, you must remove all instruments. If all instruments are not removed, you may injure the breast of the patient.

c) Angulated, manual calculation of coordinates for the MR-supported breast biopsy with the NORAS Post & Pillar Biopsy Unit on Siemens MR systems

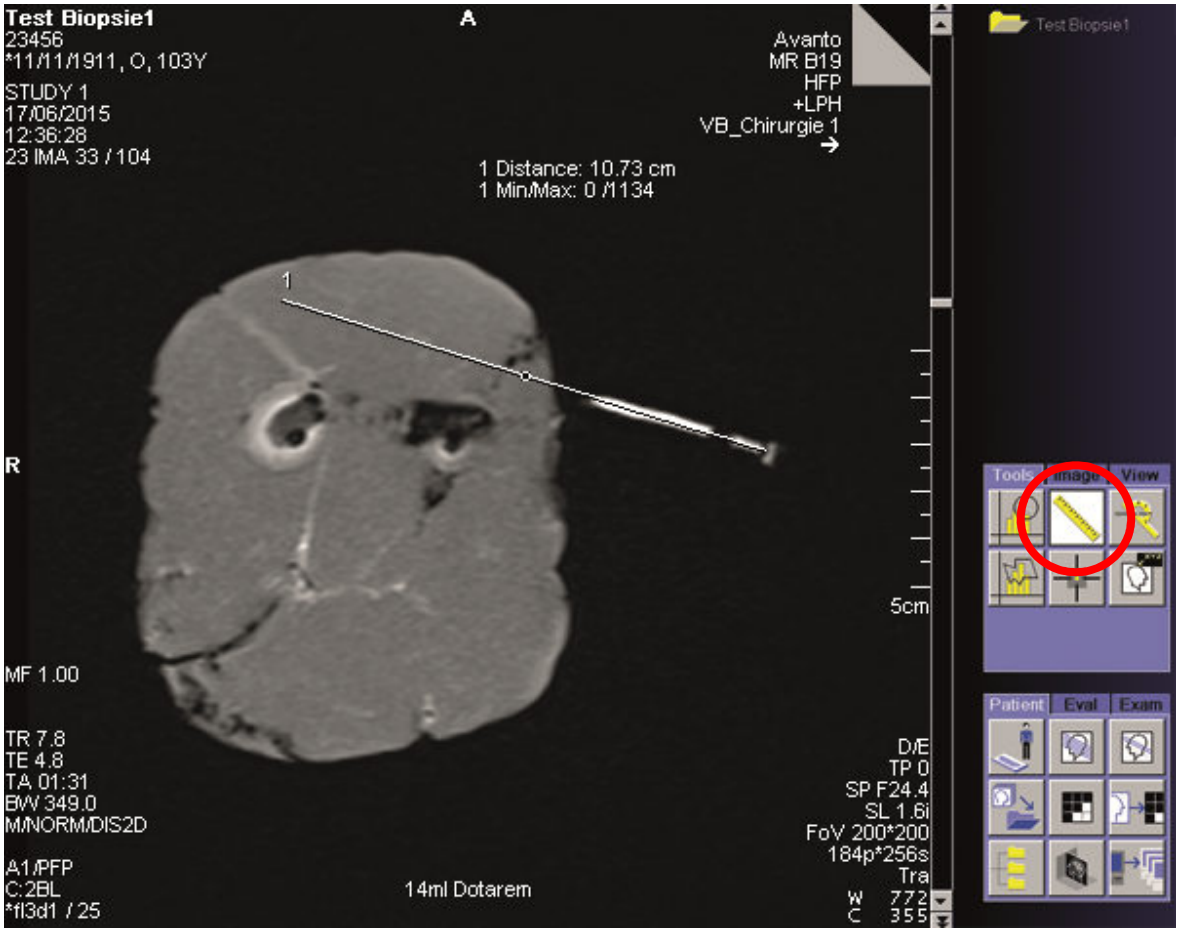
If you prefer performing an angulated biopsy, you can adjust the Post & Pillar marker with an angulation of 15 or 30 degrees toward anterior or posterior at the beginning.

The following example shows the angulation of the marker of 15 degrees toward anterior.

1. Perform a measurement with transversal slices and look for the slice where you can see the marker.



2. Start the “distance” tool (menu, right center → “Extras“ → “distance“ (ruler)) and draw a line angulated like the adjusted marker through the image and the marker. Mark that line with a left-click and select the marked line with a right-click. In the context-menu, select “copy“ (or Strg+C). By doing so, the line is copied and can be pasted into other slices.

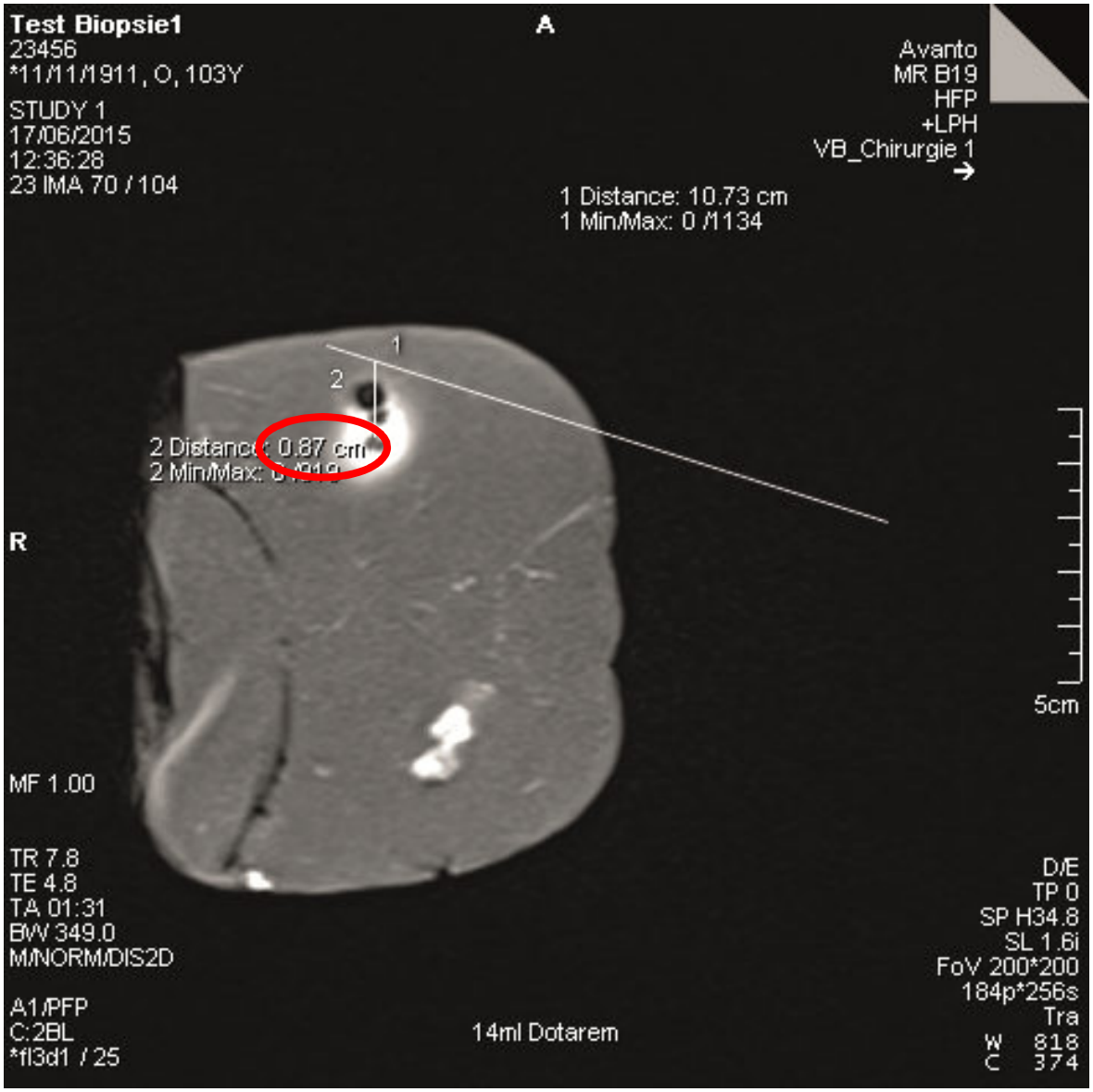


3. Scroll through the other slices until you find the lesion that you want to perform a biopsy on.

4. Right-click on this slice and select “paste“ (or Strg+V).

5. Select the “distance” tool again and measure the distance between the lesion and the reference line that you inserted in step 4. Please note these measurements on a separate piece of paper.

In this example the Post & Pillar positioning unit has to be moved 8.7 mm from the marker zero position to posterior.



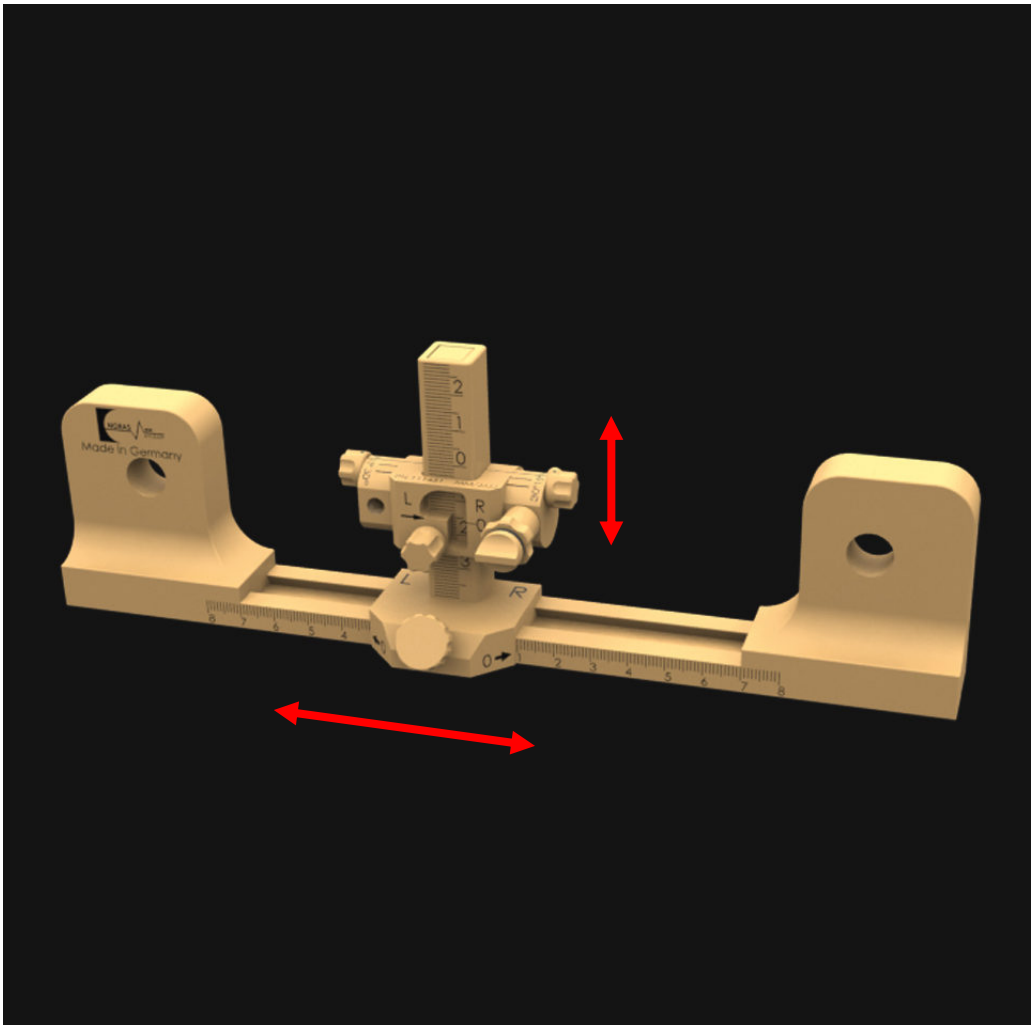
6. In order to determine the shift from head to feet (Post & Pillar positioning unit to the left or to the right), view the slice position of the marker and lesion at the transversal slices. The marker from step 1. is located on slice position (“SP“=Slice Position) F24.4, therefore 24.4 mm towards the feet from the marker zero position.

7. The lesion you have chosen in step 3. is located in our example on slice position H34.8. Hence, the sum is 24.4+34.8=59.2mm. In order to reach the lesion, you have to move the Post & Pillar positioning unit by 59.2 mm towards the head.

Note: As the position of the table marked with the laser sight seldomly shows the exact zero position one has to pay attention to either subtract or add the coordinates of the slice positions (position of marker and lesion).

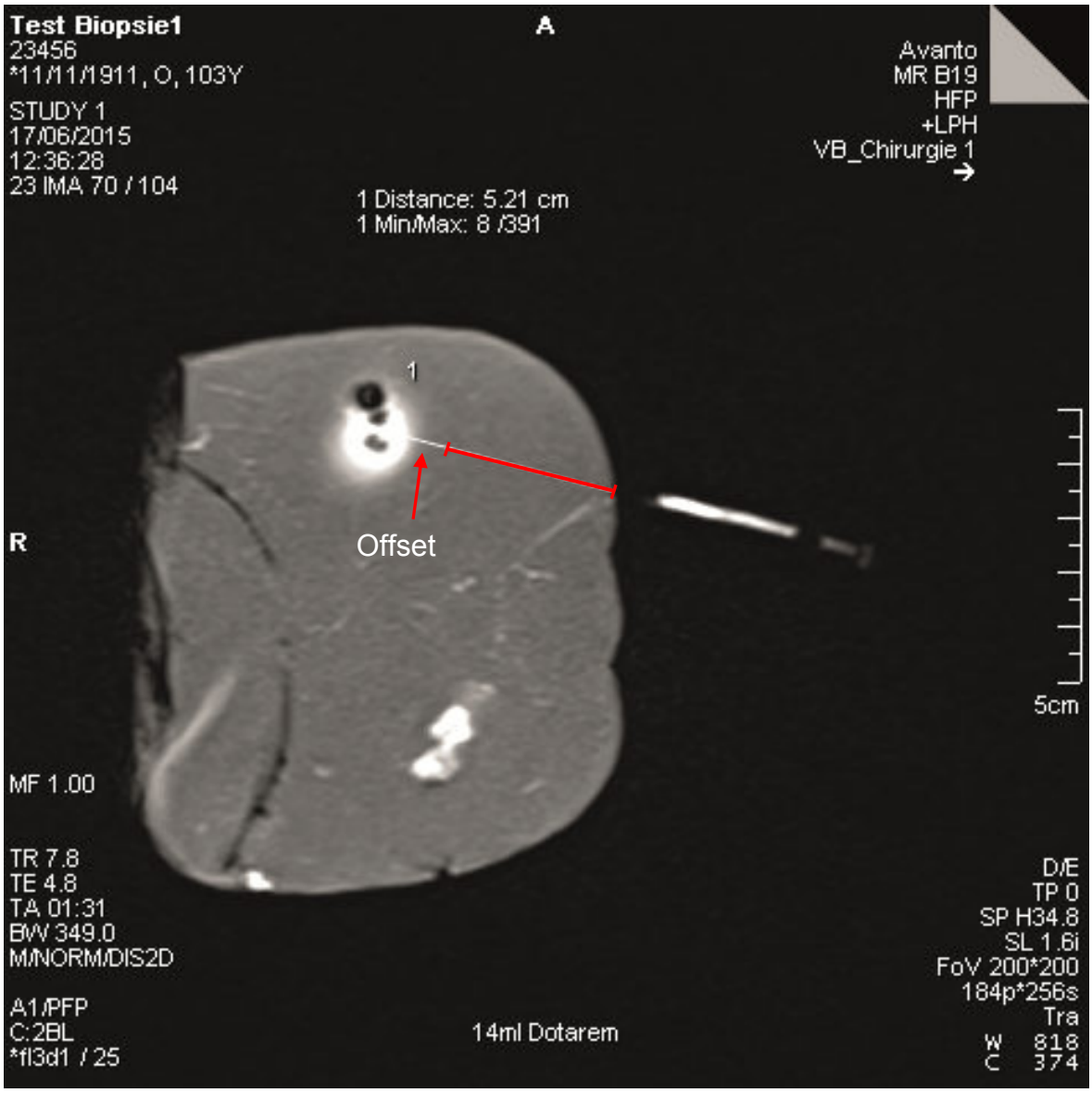
Example: When the marker of the Post & Pillar positioning unit is adjusted to zero and the slice position is H24.4 the value H34.8 would have to be subtracted.

8. Move the Post & Pillar positioning unit with the marker according to the calculated coordinates (in our example 8.7 mm upwards (posterior) and 59.2 mm towards the head).



9. Perform a control scan in order to check that the marker points at the lesion.

10. Use the “distance” tool again in order to measure the **puncture depth from the surface of the skin to the middle of the lesion** (in this case 52.1 mm). Subtract an **offset**, depending on the biopsy system (normally about **10 mm**), in order to position the cannula lie in front of the lesion.



Now replace the complete Post & Pillar needle guide for your SenoRx EnCor® vacuum biopsy system with the second sterile needle guide.

	Danger of infection
	Before intervention, the complete Post & Pillar needle guide has to be replaced with the second sterile needle guide. Failure can lead to infections of the patient.

Now puncture the breast with the trocar using this offset-corrected depth (starting at skin surface). Afterwards pull the needle out of the trocar and insert the plastic-bar into the cannula instead. The plastic-bar causes less artifact than the needle and prevents blood back-flow into the cannula.

11. Perform a control scan in order to check that the end of the needle is positioned in front of the lesion.

After the successful control scan the plastic bar can be removed from the cannula and you can start with the biopsy or inserting a localization wire.

Perform the biopsy in accordance with the instructions of your needle and/or vacuum manufacturer.

	Note
	Please note the application of the NORAS Post & Pillar vacuum gun adapter for SenoRx EnCor® with 10G or 7G doesn't require a needle guide sleeve. The cannula of the vacuum biopsy system is directly inserted into the Post & Pillar needle guide. The cannula is fixed by the locking screw of the angle adjustment.

After completion of the biopsy, clean the device parts as described in chapter 5 “Cleaning, Disinfection and Sterilization”.

	Control scan shows large or no image distortion
	Please pay attention to removing the metal trocar when inserting the cannula. When using a plastic cannula the metal trocar has to be replaced by the provided plastic stick.

	Danger of penetration through the breast
	Should, under exceptional circumstances, the needle be bent while in the breast (e.g. if the needle should strike one of the three horizontal slats after penetrating through the breast), the clip off the distally deformed needle end with a suitable, MR-compatible tool and remove the remaining trocar. Retraction of the needle with the bent end section would injure the breast.

	Danger of bruising
	Be absolutely sure to loosen the slat lateral plates before withdrawing the breast. That way bruises or injuries to the patient can be avoided.

	Danger of injury
	Before loosening and withdrawing the breast, you must remove all instruments. If all instruments are not removed, you may injure the breast of the patient.

4.2 With Grid Biopsy System

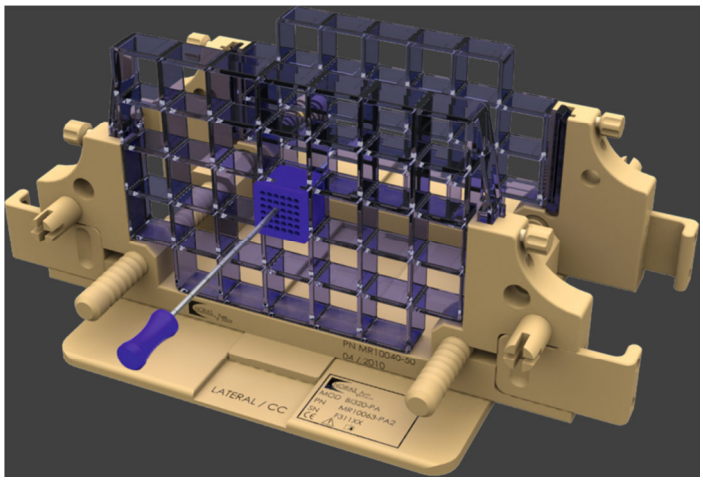
 G11	**Permanent damage to the system** The system may only be assembled by trained medical personnel. Incorrect assembly and operator errors made by untrained personnel can permanently damage individual parts of optional components and of the device itself.

 G12	**Training of personnel** The users must be trained before using the device (detailed training of the personnel for existing components).

The localization process with medio-lateral alignment of the fixation unit, lateral access and the use of the sagittal slices is next described. This applies for the use of the system with the grid for the examination of a single breast. In the case of the simultaneous biopsy of both breasts (lateral access) use a second fixation unit and a second grid on the other side and proceed in the same way.

Medial and lateral access:

Push the fixation plate with the disposable medial grid plate onto the shorter raster bars of the base plate (Ref. 111292) as far as it goes.



Slide the second fixation plate with the disposable lateral grid onto the longer raster bars of the base plate (marked „Lateral/CC“) up to the stop. Insert the base plate into the round pits of the insertion plate in the patient rest.

After aligning the complete fixation unit in medio-lateral direction, slide the fixation plate until the end of the raster bars. The fixation unit is now open as far as possible.

For medial access, insert the blocking plate into the patient rest of the side of the breast which is not to be biopsied. Now position the patient on the patient rest and immobilize the breast to be biopsied by pressing the fixation plates on the raster bars against the breast.

Be careful to ensure that the patient can lie as comfortable as possible during the entire procedure. You now have medial access below the blocking plate or lateral access from the outside.

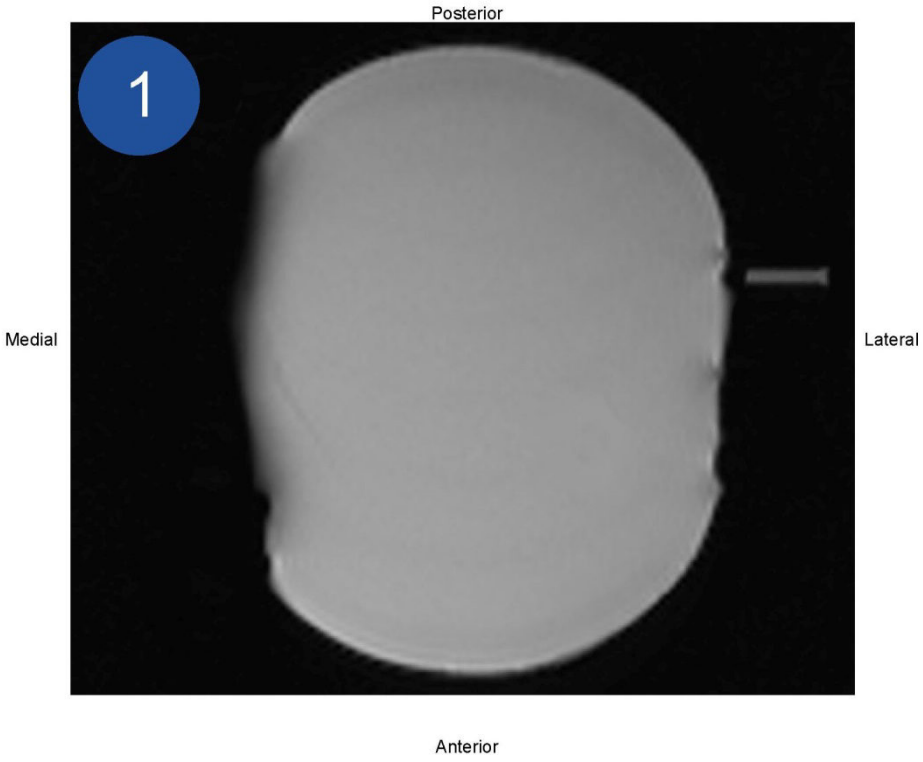
Cranial/caudal access:

Slide the fixation plate with the medial slat plate (reusable) or with a second disposable medial grid onto the shorter raster bars of the base plate (Ref. 111292) as far as it goes. Slide the second fixation plate with a disposable medial grid onto the longer raster bars of the base plate (marked “Lateral/CC”) up to the stop. Proceed as described above (access medial and lateral).

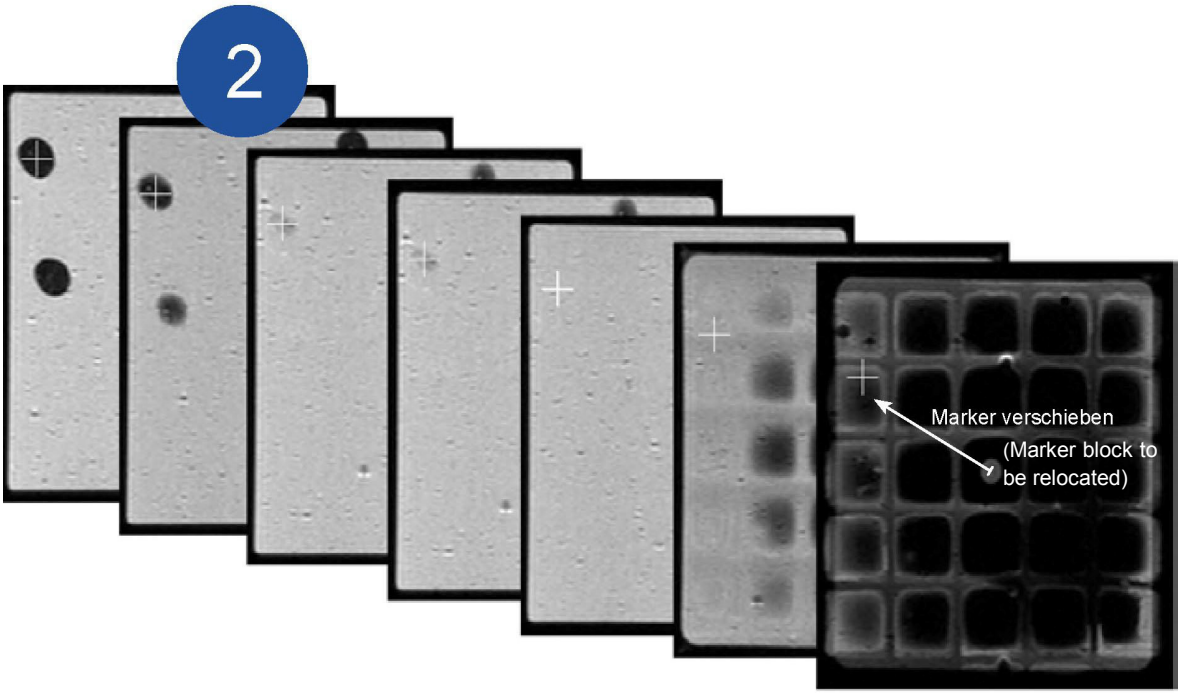
Please note that when the biopsy device is turned into the cranio-caudal direction, the MRI images must be made in the axial or transversal direction to correspond with the following description.

 G14	**Needle penetration at incorrect location**
	The breast must be correctly immobilized. If the breast is not immobilized properly, it might slip and the data delivered by the MRI might be inaccurate.

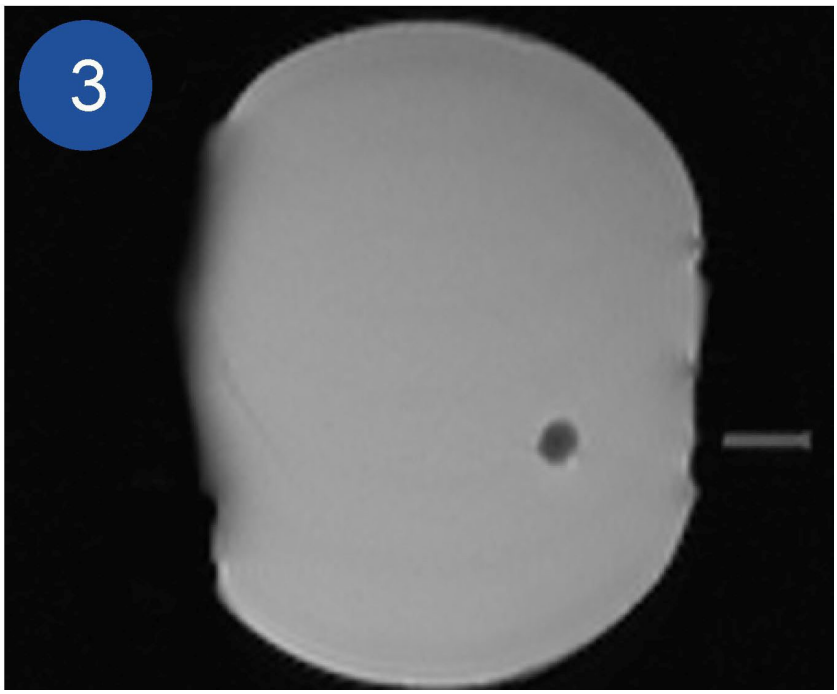
- Ensure that as much breast tissue as possible is held between the medial slat plate and the lateral grid.
- Insert the marker block supplied into the grid fixation plate.



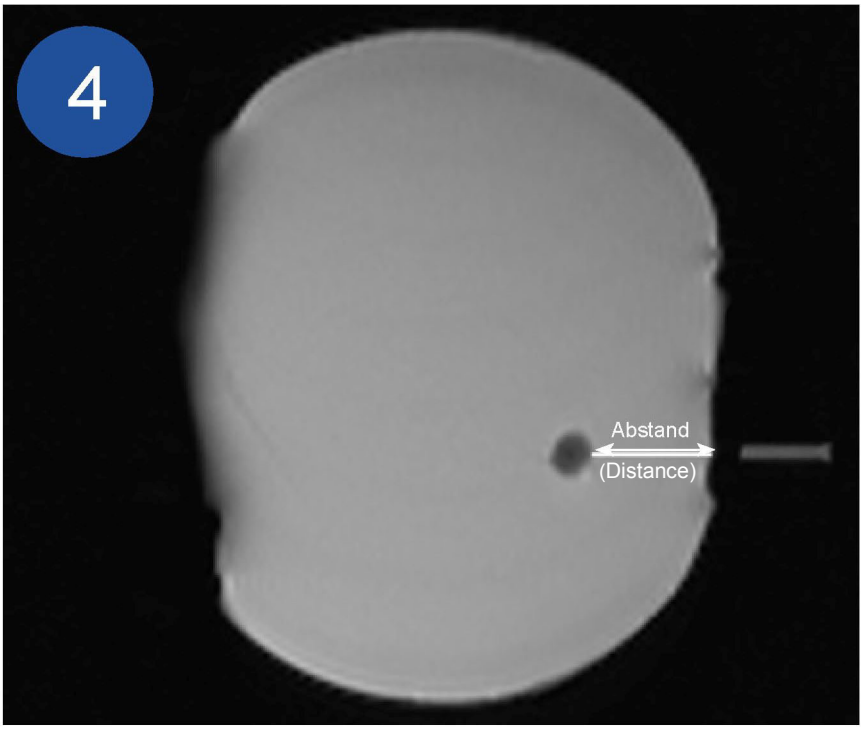
- Detect the marker block and the lesion in the MRI using sagittal slices.
- Mark the lesion with a permanent auxiliary point from the software toolbox of your MRI system.
- Copy/paste the point into all slices.
- Go to the outer lateral or medial slice and look for the grid indentation (the indentation is best viewable when sufficient tissue is placed into the square grid holes).
- Search for the copied point and the marker block pointer.
- Replace the marker block into the grid hole where the marked point is viewable.

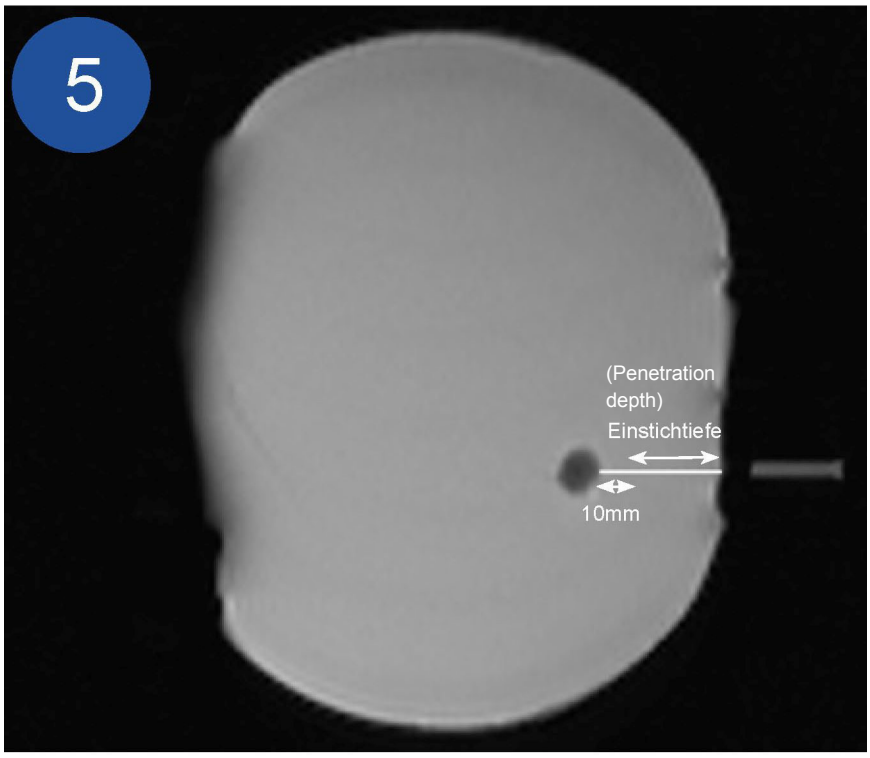


- After the axial or coronal scan the layer of the lesion and marker block can be verified in order to determine the exact puncture hole.
- In general, it is sufficient to be close to the lesion when inserting a localization wire.



- When the marker block and the lesion are in the same plane determine the **distance between the skin and the lesion** using your toolbox.





- Push the 10G needle block into the corresponding opening in the grid and, using the toolbox, determine the desired penetration point on the needle block.
- If possible (needle diameter to be considered) set a local anesthesia using the block slot that has been determined. Remove the needle block and apply an additional anesthesia, if necessary. This may be done using a bigger needle by slightly cutting the tissue with a sterile scalpel. Especially with lesions close to the surface this might be very important to avoid a delocalization.
- After re-inserting the needle block puncture the breast with the trocar of your vacuum biopsy system.
- A stop ring on the cannula marks the penetration depth to be used. Insert the cannula with the corresponding metal needle up to 10 mm in front of the lesion. After fixation on the NORAS vacuum adapter, the penetration depth of the cannula is additionally secured. For a control scan the metal needle has to be replaced with a plastic bar.

	Risk of burns
	The metal needle of the trocar has to be replaced with a plastic bar for the control scan. There is a risk of burns for the patient.

- The control scan is used to determine the exact position of the biopsy needle in front of the lesion.
- After successful control scan the plastic bar can be removed from the cannula and you can start with the biopsy or inserting a localization wire.

Perform the biopsy in accordance with the instructions of your needle and/or vacuum manufacturer.

	Note
	For biopsy with the NORAS vacuum gun adapter (grid system) for SenoRx EnCor® with 10G needles 10G needle blocks are used. When using 7G needles, a special 7G NORAS needle block (available on request) is used to fix the SenoRx EnCor® vacuum biopsy system.

After completion of the biopsy, clean the device parts as described in chapter 5 “Cleaning, Disinfection and Sterilization”.

	Control scan shows large or no image distortion
	Please pay attention to removing the metal trocar when inserting the cannula. When using a plastic cannula the metal trocar has to be replaced by the provided plastic stick.

	Danger of penetration through the breast
	Should, under exceptional circumstances, the needle be bent while in the breast (e.g. if the needle should strike one of the three horizontal slats after penetrating through the breast), the clip off the distally deformed needle end with a suitable, MR-compatible tool and remove the remaining trocar. Retraction of the needle with the bent end section would injure the breast.

	Danger of bruising
	Be absolutely sure to loosen the slat lateral plates before withdrawing the breast. That way bruises or injuries to the patient can be avoided.

	Danger of injury
	Before loosening and withdrawing the breast, you must remove all instruments. If all instruments are not removed, you may injure the breast of the patient.

5 Cleaning, Disinfection and Sterilization

WARNING:	The procedure must be followed as described. In case of inadequate cleaning, disinfection or sterilization, you carry the risk of infection. Non-compliance with the cleaning instructions may destroy the system. No warranty service will be provided for damages due to improper disinfecting. Please always wear protective gloves and carefully comply with the application times for Hepatitis B and HI viruses (See the instructions for use of the respective disinfectant solution).
Limitations on reprocessing:	Frequent processing can have an impact on these products (color changes), but do not affect the function of the product.

Note

Frequent processing can have an impact on these products (color changes), but do not affect the function of the product.

Note

Please always wear protective gloves and comply with the application times for Hepatitis B and HI viruses (See the instructions for use of the respective disinfectant solution).

INSTRUCTIONS	
Point of Use:	Remove excess soil with disposable cloth/paper wipe.
Storage and Transport:	No particular requirements. It is recommended to perform the processing of the product as soon as possible after its use. The products must be transported in a closed container.
Preparation for Cleaning:	No particular requirements. If necessary, the assembly must be disassembled into its individual components. Needle blocks could possibly be pre-cleaned by syringe or water nozzle. Cannulas and wholes must be connected in accordance to rinse body. Pay attention to correct flow. Preparation with H_2O_2 or enzymatic cleaner could be done.

Cleaning (automated): All parts made of PEEK can be cleaned by machine.	**Equipment:** Washer / disinfector **Detergent:** Example **alkaline detergent such as Neodisher® MediClean forte 0.2-1.0 vol. % (2-10 ml/l) (Dr. Weigert) at 50-60°C**. For this purpose, all agents which have been approved and released by the Robert Koch Institute (RKI) can be used in accordance with the instructions on their labels. **Procedure:** 1. Load components such that hinges are open and cannulas and holes can drain. Needle blocks could possibly be pre-cleaned by syringe or water nozzle. 2. Run cycle, minimum **5 minutes** clean and **5 minutes** rinse. 3. When unloading, check cannulas, holes etc. for complete removal of visible soil. If necessary, repeat cycle or use manual cleaning.	**Applicable only for:** Post & Pillar Adapter for SenoRx EnCor® (consisting of: Post & Pillar Marker for SenoRx EnCor®, Post & Pillar Needle Guide for SenoRx EnCor®) Grid Needle Block Adapter for SenoRx EnCor®

Disinfection (automated): All parts made of PEEK can be cleaned by machine.	**Disinfectant: Depending on RDG and Vario-TD-program you can select on disinfectant which has been approved and released for automated disinfection.** **Procedure:** If automated disinfection is employed, a final rinse at **90°C** for **5 minutes** may be used to effect thermal disinfection. The parts such as needle guides and needle blocks can be disinfected in accordance with the same procedure in an ultrasonic bath. The assembly must be disassembled into its individual components, so that an optimal disinfection is guaranteed.	**Applicable only for:** Post & Pillar Adapter for SenoRx EnCor® (consisting of: Post & Pillar Marker for SenoRx EnCor®, Post & Pillar Needle Guide for SenoRx EnCor®) Grid Needle Block Adapter for SenoRx EnCor®

Cleaning and Disinfection (manual): All parts made of PEEK can be cleaned manually.	**Detergent:** Example **Sekusept® PLUS (Ecolab) 4.0 vol. %, Korsolex® Plus 3.0 vol. % with exposure time of 15 minutes**. For this purpose, all **aldehyde-free** surface disinfectants which have been approved and released by the RKI and the VAH can be used in accordance with the instructions on the label. The cleaning of the parts could be done manually in immersion or ultrasonic bath for **10-30 minutes**, preferable at temperatures of up to **50°C**. **Procedure:** 1. Rinse excess soil from components. 2. Using soft brush, apply detergent solution to all surfaces ensuring that hinged components are cleaned in both open and closed positions. 3. The part is held under running water for **5 minutes**. In this case, the running water must flow through the cannulas. The blind holes must be repeatedly filled and emptied. 4. The parts must be cleaned as long as no visible blood or tissue residues more on the products to be seen. For manual disinfection, it is advisable to insert the parts (for expected parts see left column) in the solution immediately after use. Ensure that the parts are completely submerged in the solution. Take the parts from the solution after the described time	**Applicable only for:** Post & Pillar Adapter for SenoRx EnCor® (consisting of: Post & Pillar Marker for SenoRx EnCor®, Post & Pillar Needle Guide for SenoRx EnCor®) Grid Needle Block Adapter for SenoRx EnCor®

	15 minutes and rinse by water (the quality of water must be at least equal to drinking water, better would be using aqua. Demineralized water). Changing in color due to continuous disinfection cannot be excluded, but can be largely prevented by sufficient rinsing after each use. The solution is distributed on the surfaces by a fluff-free cloth. The disinfectant permeates the dirt particles and because of mechanical forces (pressure, abrasion), this ensures effective cleaning. Additionally, the wiping motion ensures that spores, which are resistant to the disinfectant, will be removed. The cloth must be replaced after the disinfection in order to prevent the spreading of the spores on other areas. Moreover, it is essential that the wiping solution is renewed regularly (daily).	

Drying:	When drying is achieved as part of washer/disinfector cycle, do not exceed **50°C**.
Maintenance, Inspection and Function Testing:	Blunt or damaged parts should be discarded. Hinged parts: Check for smooth movement of hinge without excessive “play“. Locking (ratchet) mechanism should be checked for action. All parts: Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Check components with long slender features (particularly rotating components) for distortion. Where components form part of a larger assembly, check assembly with associated components.
Packaging:	**Singly:** A standard packaging material may be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. **In sets:** The parts may be loaded into dedicated instrument trays or general-purpose sterilization trays. Ensure that cutting edges are protected and do not exceed the maximum loading per tray. Wrap the trays using appropriate method. See also guidance of DGSV, RKI and DIN EN ISO 11607-1.

Sterilization:	**Steam sterilization:** The following items may be subjected to steam sterilization, but not on basis of STERRAD®: Post & Pillar Adapter for SenoRx EnCor® (consisting of: Post & Pillar Marker for SenoRx EnCor®, Post & Pillar Needle Guide for SenoRx EnCor®) Grid Needle Block Adapter for SenoRx EnCor® **Procedure:** 134°C; 3.04 bar; 5 min The effectiveness of steam sterilization according to the procedure mentioned above has been validated by Dr. Schwarzkopf.

	Warning
	Markers must be emptied prior to sterilization!

Storage:	Safe, dry, dust-free and protected from light Constant temperature (23°C +/- 2°C) Constant humidity (below 60% rel. humidity)
Additional Information:	When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.
Manufacturer Contact:	See chapter 7

 G17	**Danger of destruction** Improper disinfection may result in malfunction of the device. Non-respect of the disinfection instructions may cause the destruction of the device! No warranty service will be provided for damages due to improper disinfection.

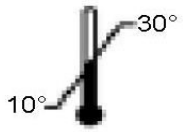
 G03	**Danger of infection** The disinfection instructions must be followed. In case of inadequate disinfection the risks of infection arise to user and / or end user.

 G18	**Danger of destruction** Improper sterilization may result in malfunction of the device. Non-respect of the sterilization instructions may cause the destruction of the device! No warranty service will be provided for damages due to improper sterilization.

 G04	**Danger of infection** The sterilization instructions must be followed. In case of inadequate sterilization the risks of infection arise to user and / or end user.

6 Storage and Waste Disposal

6.1 Storage

	Following its use and the required cleaning, disinfection and sterilization, the device should be stored at room temperature in a dust-free, UV radiation-protected location (min. 10°C, max. 30°C). In the case of re-sterilized vacuum gun-adapters, you must not exceed the maximum storage period (currently 6 months if stored in single or double packaging in protected storage in dust-tight containers, cabinets, drawers or similar places).

- Relative Humidity: Min.10%, Max. 95%
- Air Pressure: Min. 500 hPa, Max.1060 hPa

6.2 Waste Disposal

All of the materials used in the manufacture of the system components can be conveniently recycled and therefore do not present any particular or unusual hazards during their disposal.

Prior to disposal, the system must be disinfected as described above to eliminate any risk of infection.

We would be happy to provide you with additional information about disposal upon request.

7 Important Addresses

Manufacturer (product development and production)

	NORAS MRI products GmbH Leibnizstrasse 4 97204 Hoechberg Germany Telephone: +49 931/2 99 27-0 Telefax: +49 931/2 99 27-20 E-Mail: mri@noras.de Internet: www.noras.de

Your notes

Your notes